

June 28, 2011

Margaret A. Hamburg, Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Room 2217  
Silver Spring, MD 20993

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

**Re: Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments (FDA-2011-F-0172)**

**Re: Food Labeling; Calorie Labeling of Articles of Food in Vending Machines (FDA-2011-F-0171)**

Dear Commissioner Hamburg:

Congress established the Office of Advocacy (Advocacy) under Pub. L. 94-305 to represent the views of small business before Federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA); as such the views expressed by Advocacy do not necessarily reflect the views of the SBA or of the Administration. Section 612 of the Regulatory Flexibility Act (RFA) also requires Advocacy to monitor agency compliance with the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act.<sup>1</sup>

**Legislative and Regulatory Background**

On March 23, 2010, the President signed into law the Affordable Care Act (ACA) (Pub. L. 111-148). Section 4205 of the ACA, which principally amends sections 403 and 403A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343 and 343-1), requires chain restaurants and similar retail food establishments (SRFE) with 20 or more locations doing business under the same name and offering for sale substantially the same menu items, as well as operators of 20 or more vending machines, to disclose certain nutrition information for certain food items offered for sale so that consumers can make more informed choices about the food they purchase. While certain provisions of Section 4205 became law when the ACA was signed by the President, other provisions required the

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<sup>1</sup> Pub. L. No. 96-354, 94 Stat. 1164 (1981) (codified at 5 U.S.C. §§ 601-612) amended by Subtitle II of the Contract with America Advancement Act, Pub. L. No. 104-121, 110 Stat. 857 (1996). 5 U.S.C. §612(a).

Food and Drug Administration (FDA) to issue rules before the requirements could be enforced.

On August 25, 2010, the FDA published a guidance document in the *Federal Register* designed to provide industry with information on the effect of Section 4205 of the ACA on State and local menu and vending labeling laws.<sup>2</sup> On November 5, 2010, the FDA published a notice in the *Federal Register* requesting public comment on the recordkeeping and mandatory third party disclosure provisions of Section 4205 of the ACA.<sup>3</sup> On January 25, 2011, the FDA announced the withdrawal of the guidance, noting that the agency intended to complete the notice and comment rulemaking process before initiating enforcement activities based, in part, on extensive comments on the draft guidance submitted to the agency.<sup>4</sup> On April 6, 2011, the FDA published two proposed food and calorie labeling rules in the *Federal Register*, one for chain restaurants (chain restaurant rule), the other for vending machines (vending machine rule).<sup>5</sup>

### **Advocacy Involvement**

My office has been closely following the menu labeling issues outlined by the FDA in these proposed rules since representatives from the chain restaurant and vending machine industries contacted my office with concerns about the information sought in FDA's November 2010 notice. While the industry representatives that approached Advocacy were supportive of the need for national menu labeling, they were concerned about the FDA's interpretation of certain provisions of Section 4205, and the economic impact that any regulations promulgated by the FDA would have on their respective industries.

On January 4, 2011, Advocacy filed comments with the FDA that provided the agency with numerous concerns voiced by various small business groups that would be impacted by any nutrition labeling regulations promulgated under ACA. Advocacy and the stakeholders were encouraged when the FDA withdrew its guidance to industry on January 25, 2011, and decided to proceed through notice and comment rulemaking. However, after the proposed rules were published many of the industries' concerns remained unaddressed as the proposed rules were very similar in many respects to the guidance document withdrawn by the FDA. Also, the proposed rules did not offer an increased degree of certainty and clarity that affected stakeholders need to comply with Section 4205 of the ACA. These industry issues along with Advocacy's concern with certain aspects of the RFA analysis form the basis for these comments.

### **The FDA should consider industry alternatives seeking to minimize the proposed rules' impacts because of difficulty assessing costs.**

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<sup>2</sup> 75 Fed. Reg. 52427 (August 25, 2010).

<sup>3</sup> 75 Fed. Reg. 68361 (November 5, 2010).

<sup>4</sup> 76 Fed. Reg. 4360 (January 25, 2011).

<sup>5</sup> 76 Fed. Reg. 19192 (April 6, 2011) and 76 Fed. Reg. 19237 (April 6, 2011).

The FDA's Preliminary Regulatory Impact Analysis (PRIA) in the chain restaurant proposed rule estimated that there would be approximately 278,600 covered establishments organized under 1,640 chains.<sup>6</sup> The agency acknowledged that it had difficulty assessing the cost of this regulation because of the "relatively complicated ownership structures in some of the covered sectors."<sup>7</sup> The FDA noted that the majority of costs of the proposed rule will be borne at the establishment level, in particular, the cost of new menus and of employee training.<sup>8</sup> The FDA's regulatory analysis estimated that the initial mean estimated cost of complying with the proposed rule is \$315.1 million, with an estimated mean ongoing cost of \$44.2 million.<sup>9</sup> Initial costs are estimated to be \$1,100 per establishment.<sup>10</sup> The cost per establishment is qualified by the FDA when it noted that, "these averages do not show the very wide range of costs that individual establishments and chains will bear, based on their very different approaches to nutritional analysis, menu design and overall market niche."<sup>11</sup>

The PRIA for the vending machine rule estimated that there would be approximately 10,800 operators under the proposed requirements, controlling between 4 million and 5.6 million machines that sell covered foods (97% are deemed small businesses based on the U.S. Small Business Administration's size standards).<sup>12, 13</sup> The FDA estimated that the initial mean estimated cost of complying with the proposed requirements is \$25.8 million, with an estimated mean ongoing cost of \$24 million. Per operator costs are estimated to be \$2,400, with the average per machine cost of less than \$10 annually.

Because the FDA concluded that both rules would have a significant impact on a substantial number of small entities, the agency complied with the RFA by preparing an Initial Regulatory Flexibility Analysis (IRFA).<sup>14</sup> The IRFA in both rules noted that the FDA built substantial flexibility into the requirements by allowing affected entities to use a variety of approaches to comply with the proposed regulations. In the chain restaurant rule the FDA suggested that it would be difficult to tie flexibility to the size of the firm as it could lead to confusion for customers and competitors and possibly result in higher costs.<sup>15</sup> The RFA requires that the IRFA shall contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of the applicable statutes and which minimize any significant economic impact of the proposed rule on small entities.<sup>16</sup>

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<sup>6</sup> Id. at 19222.

<sup>7</sup> Id.

<sup>8</sup> Id. at 19224.

<sup>9</sup> Id. at 19222.

<sup>10</sup> Id.

<sup>11</sup> Id.

<sup>12</sup> Food Labeling: Calorie Labeling of Articles of Food in Vending Machines NPRM, Preliminary Regulatory Impact Analysis (March 2011), page 8.

<sup>13</sup> On page 7 of the vending machine PRIA, the FDA adopts The National Automatic Merchandizing Association's estimate that there are 13,500 companies operating vending machines in the U.S., yet the agency's cost estimate assumes 10,800 operators which may cause an underestimation in the costs.

<sup>14</sup> 76 Fed. Reg. at 19224 (chain restaurant rule) and 76 Fed. Reg. at 19249 (vending machine rule).

<sup>15</sup> 76 Fed. Reg. at 19224.

<sup>16</sup> 5 U.S.C. §603(c).

The RFA requires that the agency promulgating any regulation analyze the impact of the proposed rule on small businesses and entertain reasonable alternatives designed to lessen the impact of the rule on those businesses. This analytical requirement endeavors to ensure that the agency provides the public with a description of the costs and benefits of the rule. Industry representatives that approached Advocacy were in widespread agreement that the FDA's regulatory analysis does not adequately analyze the impacts of the rule on affected businesses, failed to take a look at the upper end of the cost range, and therefore may have underestimated the true costs of the regulation on their businesses. The same representatives suggested that the costs of this regulation would be lessened if the FDA clarified certain provisions of the rule and entertained reasonable alternatives. Advocacy hopes that the FDA will consider some of the suggestions/alternatives recommended by the affected industries contained in this comment letter while promulgating the final rule.

**Affected industries believe that the FDA's cost assumptions are underestimated.**

There was consensus among the industry groups, individual small businesses and franchisees that the FDA needs to do a better job analyzing the impacts associated with the two proposed rules. The National Council of Chain Restaurants (NCCR) surveyed representative members of their organization and found that costs for chains with between 20 and 4500 locations were \$1,333 per establishment. While not substantially more than FDA's estimate of \$1,100 per establishment it should be noted that averaging the costs over chains with vastly different numbers of stores likely understates the costs for smaller chains, where typical costs per establishment may be higher because less of the burden of testing and standardized design work may be borne by a large corporate franchisor.

Representatives from the pizza industry also agree that the FDA's \$2,400 impact estimate for industry is low. Dominos Pizza<sup>17</sup> estimates that the current cost to print a menu board is \$100, but adding calorie information to these menu boards increases the cost to \$900 due to extra labor to add calories to each menu. Franchisees have a number of items they are required to carry but also have a number of optional items they may choose to carry as well, and they set their own pricing. As a result, each franchisee's menu board varies and each must be individually produced to create accurate calorie information. Stores typically change their menu boards twice a year, but in years where Domino's unveils new products, stores may have to change their menu boards four times per year. For a franchisee, this means that calorie labeling menu boards alone will cost \$1,800-\$3,600 per year. In addition, franchisees will be required to pay an addition \$81 for nutrition brochures, and will have to invest approximately \$833 labor hours per store to comply with menu labeling requirements. It is estimated that Domino's Pizza franchisees could have to spend up to \$4,000 per store to menu label each year, which takes away on average about 10% of the profits of that stores.

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<sup>17</sup> While corporate Dominos is a large business, individual franchisee owners will be required to pay many of the proposed rule's costs. The franchisees are small businesses under the RFA.

### **Industry alternatives thought to lessen economic impact.**

- a) The FDA should withdraw the proposed “80-120” requirement for nutritional disclosures and utilize a “reasonable basis” standard as was intended by the ACA.

Section 4205 of the ACA states that, “a restaurant or similar retail food establishment shall have a reasonable basis for its nutrient disclosures.” The proposed rule seems to require a more stringent standard based on already existing rules that govern commercially manufactured and packaged foods known as the “80-120” rule. Industry representatives suggest that the FDA erred in its interpretation of Section 4205 and exceeded its authority when it proposed the 80-120 requirement.<sup>18</sup> Affected chain restaurants maintain that it is unreasonable to require restaurants to obtain a nutritional disclosure with the degree of consistency expected in manufacturing facilities as restaurant food is inherently variable in its presentation. Restaurant food is prepared individually at a customer’s request, ingredients are obtained in many instances from multiple suppliers, and standardized recipes are hand prepared. Restaurant representatives argue that the FDA should require a nutritional declaration that is consistent with the ACA’s legislative intent, and the reasonable basis definition the FDA itself promoted in its Food Labeling; Nutrient Content Claims and Health Claims rule in 1996.<sup>19</sup> In the Claims rule the FDA noted, “the way in which a restaurant determines the nutrient content of a food or meal, and the way in which nutrition information is communicated to consumers, may be different for restaurant foods than for foods from other sources. . . . [f]or compliance purposes, a restaurant is required to provide information on its reasonable basis for making a claim.”<sup>20</sup>

The 80-120 requirement changes a 20-year FDA policy for restaurants. Industry representatives suggest that until the FDA brings the definition of “reasonable basis” into line with Section 4205 of the ACA, many of the covered industry sectors cannot be expected to test their food products for caloric content and finalize their menu boards. Until a decision is made as to the testing standard to be used in the chain restaurant rule, covered entities are exposed to liability and litigation risks for being out of compliance with the 80-120 requirement. Based on the totality of these concerns, the representatives question whether FDA’s proposed six-month implementation period from the effective date can be met, and they request one-year.

The 80-120 requirement also raises other serious issues for affected entities because the chain restaurant rule does not discuss or analyze FDA’s plans for enforcement – information deemed vital by affected entities. For example, if a chain restaurant is found to be out of compliance in New York City, what action does the business need to take to change menus and menu boards throughout the rest of the country? If a supplier

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<sup>18</sup> The proposed chain restaurant rule divides nutrients into Class I added nutrients and Class II naturally occurring nutrients. Class I protein or dietary fiber must be present in at least the declared amounts, and Class II protein, total carbohydrates, and dietary fiber must be present in at least 80 percent of the declared levels. Calories, sugars, total fat, saturated fat, trans fat, cholesterol, and sodium cannot exceed their declared levels by more than 20 percent. 76 Fed. Reg. 19218.

<sup>19</sup> 58 Fed. Reg. 2387 (February 2, 1996).

<sup>20</sup> Id.

reformulates a food product, does the chain restaurant have to then incur the cost of retesting and amending menus and menu boards outside of the menu board cycle? The chain restaurant rule also encourages establishments with less than 20 locations to voluntarily register with the FDA and become part of the Federal requirements.<sup>21</sup> The more stringent 80-120 standard and some of the aforementioned concerns raised by the industry representatives will only serve to act as a disincentive for restaurants with less than 20 locations to comply with the nutritional labeling requirements of the proposed rule.

- b) The FDA should revisit its “primary writing” requirements, and should apply additional flexibility to chain pizza restaurants in an effort to reduce burden.

The pizza industry suggests that the potential exists for increased compliance costs as a result of the FDA’s definition of “primary writing.” In the chain restaurant rule the FDA concluded that a menu or menu board includes “any writing” that a consumer uses to make a purchasing decision.<sup>22</sup> FDA explained that it is interpreting “primary writing” from a consumer’s vantage point and therefore will interpret “menu or menu board” to include any writing any consumer might use. Industry representatives believe that the FDA went beyond the statutory intent of the ACA. Section 4205 of the ACA defines “menu or menu board” as “the primary writing of the restaurant or other similar retail food establishment from which a consumer makes an ordering selection.”<sup>23</sup>

By expanding the definition of primary writing, the FDA requires that every menu or menu board, internet menu or other writing that a consumer would use to order must contain nutrition information (not including advertisements). The industry believes that FDA’s interpretation of the statutory language is expensive, time consuming, and burdensome.

The industry suggests that other aspects of the chain restaurant rule are equally as burdensome on covered entities and that the FDA should provide more flexibility on how to comply with the proposed rule’s requirements. The chain restaurant rule states that multi-serving foods, such as a bucket of chicken or pizza, are deemed to be standard menu items and therefore the covered entity must provide the consumer with the required nutritional information. The industry representatives believe that the consumer gets little information from obtaining the total caloric information from a bucket of chicken, and that the consumer would obtain greater benefit from nutritional information based on serving size, e.g. the calories contained in a piece of chicken. By requiring that the covered entity label the entire multi-serving food the consumer would have to do their own calculation to determine the calories in a slice of pizza, for example.

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<sup>21</sup> 76 Fed. Reg. 19218.

<sup>22</sup> *Id.* at 19201.

<sup>23</sup> 21 U.S.C. § 343(q)(5)(H)(xi).

The proposed chain restaurant rule requires that covered entities must declare the calories for food that comes in different flavors, varieties or combinations as a range for standard menu items.<sup>24</sup> Dominos representatives point out that there are 34 million ways to order a Dominos pizza and with all those options a nutritional range can vary by 2000 calories. They believe that such a wide range of caloric information is useless to the consumer. The representatives suggest that the FDA allow them to provide calorie-labeled information on standard-build pizzas, with tools made available to consumers (online calculators or detailed nutrition brochures) that would allow them to identify how many calories are in a more customized pizza.

- c) FDA should allow the vending machine industry a range of labeling solutions and explain its plans for enforcement.

The vending machine industry encourages the FDA to ensure maximum flexibility in the final vending machine rule by allowing a range of labeling solutions. The representatives believe this is vital because of the wide variety of vending machines in existence, and because the overwhelming majority of regulated entities will be small businesses with low profit margins. The National Automatic Merchandising Association (NAMA) estimates that a vending business with 20 machines may average an annual profit of only \$3,559.20. While the representatives believe that the FDA has shown greater flexibility since the publication of its initial economic analysis related to menu labeling for vending machines, the industry believes that areas exist for even greater flexibility in the following areas:

Vending representatives believe that the FDA should not require a specific type size or font for such signage. With more than 300 designs of vending machines in service, flexibility in type size, font style and colors should be allowed to the operator.

Vending machine representatives are concerned with FDA's requiring all food products to display calories per package as opposed to calories per serving. They recommend that food and beverages have a range for disclosure. For food and beverages below 20 ounces, the calories should be listed per package. However, for food and beverages with more than 20 ounces, calories should be labeled per serving. For gum and mints, calories should be reported per serving.

The representatives recommend that the FDA allow the use of caloric ranges, similar to those provided for restaurants. While food and beverage vending machines are designed to provide a consistent product each time it is dispensed, slight variations in servings can result. This will reduce the costs of compliance with the proposed rule and limit the industries' exposure to litigation.

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<sup>24</sup> 76 Fed. Reg. 19207.

Affected industry representatives believe that where calorie information is not available from a food manufacturer or supplier, that a vending operator should be allowed to use nutrient databases, cookbooks, laboratory analyses or other means to accurately determine calorie information. The costs of calorie analysis will be considerable, and to minimize the cost to small businesses, it's important to allow a variety of tools to ascertain an accurate calorie count. Representatives do not believe that the FDA should require a vending machine operator to provide the FDA the method or information on which they relied to determine the total calories posted for the vending machine food.

Vending machine representatives believe that the FDA underestimated the frequency of restocking machines and changing labels in its projections. In almost all situations, machines are restocked and serviced at least every 5 weeks. During this restocking, it is highly likely that individual snacks and drinks could be replaced with different varieties, which would require new labeling. It is important to note that the foods which are stocked vary widely depending on the location. One site may have a very different group of snacks and drinks than a site in the next building. This very wide variety of potential product mixes within a particular machine or locations will mean that a wide variety of labels and frequent changes may be required. This more frequent restocking will occur in the estimated 1.3 million snack machines. NAMA estimates that a typical vending machine will have to be re-labeled at least 10 times per year (every 5 weeks), and potentially 17 times a year (every 3 weeks). Based on the above scenario industry representatives believe that the FDA should allow vending machine operators to use a general posting of the nutritional information of all products in the warehouse to be placed in close proximity to the machines to limit the need and cost associated with the relabeling of menus.

Affected vending machine operators note that the proposed vending machine rule does not discuss what steps the FDA will take for enforcement of the proposed rule. This information should be disseminated to the industry for transparency purposes. They also feel that the proposed 1-year compliance requirement is not sufficient and that a more realistic compliance period is 2-years.

## **Conclusion**

Advocacy requests that the FDA consider the affected industries' comments into consideration as they finalize these proposed rules. Also, in light of the economic impact data provided by the affected industries, Advocacy encourages the FDA to revisit some of its cost assumptions in the final rule.

The RFA requires that final rule must contain a Final Regulatory Flexibility Analysis (FRFA).<sup>25</sup> Section 604(a)(2) provides that the FRFA must summarize significant issues raised by the public comments in response to the IRFA and an assessment by the agency

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<sup>25</sup> 5 U.S.C. §604.

of those issues. Section 604(a)(5) requires that the agency must include a statement containing the factual, policy and legal reasons for selecting the alternative adopted in the final rule and why each of the other significant alternatives were rejected. Advocacy encourages the FDA to entertain and analyze the aforementioned alternatives recommended by the affected stakeholders, and to discuss its reasons for accepting or rejecting those recommendations in the final rule.

If you have any questions or concerns, please do not hesitate to contact me or Linwood Rayford at (202) 205-6533, or [linwood.rayford@sba.gov](mailto:linwood.rayford@sba.gov).

Sincerely yours,

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Cc: Cass R. Sunstein, Administrator, Office of Information and Regulatory Affairs