January 4, 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: 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 of 2010 (FDA-2010-N-0567)

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.[1]

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

[1] 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).

business under the same name and offering for sale substantially the same menu items (hereinafter 'chain retail food establishments''), as well as operators of 20 or more vending machines (hereinafter ''chain vending machine operators''), 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.

On November 5, 2010, the U.S. Food and Drug Administration (FDA) published in the *Federal Register* a notice (notice) requesting public comment on the recordkeeping and mandatory third party disclosure provisions of section 4205 of the Patient Protection and Affordable Care Act of 2010 (PPACA).[2] FDA invited comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.[3]

My office held discussions with interested stakeholders, including the National Automatic Merchandising Association (NAMA) and the National Restaurant Association (RA), who voiced their concerns that the FDA has underestimated the recordkeeping burden and the number of affected business entities that will be impacted by the forthcoming regulation. Both NAMA and RA believe that there will be a significant impact on a substantial number of small businesses. This concern is buttressed by FDA's own estimates that the regulatory burden will be large - including 31,408 recurring hours for vending machine operators' recordkeeping, and 14,037,400 recurring hours for third party disclosure.[4]

Both NAMA and the RA stress that they did not oppose the legislation that resulted in the FDA's issuance of this notice as they are sensitive to the problems associated with childhood and adult obesity in the United States. However, because many of the impacted businesses will be small, they wish to ensure that the FDA complies with the RFA by analyzing the economic impacts associated with implementation of the law and takes into consideration reasonable alternatives that will serve to mitigate those impacts. Advocacy agrees that in this circumstance an RFA analysis is appropriate. Advocacy hopes that the FDA will take the following industry concerns and comments, which are grouped into the four categories outlined by the FDA in the Notice, into consideration as it moves forward with the regulatory process:

[2] 75 Fed. Reg. 68361 (November 5, 2010).
[3] 75 Fed. Reg. 68362.
[4] 75 Fed. Reg. 68362.

(2) The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

- NAMA points out the PPACA exemption for vending operators operating 19 or less machines will not reduce the burden on the industry significantly. NAMA research indicates that the smallest size businesses surveyed have less than $2 million in annual sales, yet on average the typical vending company owns 259 vending machines. Based on this data NAMA concludes that any regulation promulgated by the FDA will impact 90 to 95 percent of the industry.

- Industry representatives believe that the FDA's estimate of the number of impacted vending companies is too low. In the notice the FDA estimates that approximately 7 million machines are serviced by 5,000 operators, for a per operator average of 1,400 machines.[5] NAMA estimates that there are 10,500 vending operators in the U.S. that will have to comply with the nutritional disclosure rule. Based on the NAMA research at least 90% of the vending companies will be impacted, which is closer to 9,450 companies.

- RA believes that most medium to large chains expect to spend several million dollars to conform their systems (including nutritional analysis, menu/menu board design, replacement, and training costs) to the FDA's labeling regulations. As many franchised restaurant models the costs associated with menu, menu board and drive thru replacement are the responsibility of the franchisee, a significant proportion of these costs will fall on small business owners. As a result, RA suggests that the FDA may have underestimated that cost of labeling changes necessary to comply with the regulation.

- The FDA has underestimated the number of drop-cup beverage vending machines (300,000) in the notice. Industry representatives note that the 2009 Census of the Industry published in the Vending Times estimated that there were 330,000 hot beverage vending and 60,000 cold-cup machines, raising the estimate of beverage vending machines to 390,000.

- NAMA believes that the FDA has underestimated the frequency at which the vending machines would be restocked. The FDA estimates a recurring hourly burden of one hour per machine, two times per year to install the displays. Industry representatives argue that the FDA's assumption does not account for the frequency that vending machines are restocked and that different varieties of product are installed. As a result NAMA estimates that a typical vending machine will have to be re-labeled at minimum approximately 10 times per year.

[5] 75 Fed. Reg. 78364.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected.

- In the notice the FDA estimates that 1,069 restaurant chains and 231,000 outlets will be required to comply with nutritional labeling. According to the RA, the difference between their data and FDA's data on the number of restaurant chains and establishments can be attributed to a lack of clarity on the definition of "restaurant." The industry is waiting for FDA to define terms such as restaurant in the forthcoming rulemaking.

- In the notice the FDA assumes that because all vending machines sell food that is previously manufactured and packaged, calorie analysis and production of calorie analysis displays will be most efficiently done at the manufacturer level instead of operator level (those manufacturers also already keep the caloric information which is subject to the National Labeling Education Act).[6] The FDA suggests that the food manufacturers include a set of calorie label stickers which will minimize the cost of the regulation on vending operators. The net effect of this scenario is that the FDA has shifted the burden of labeling compliance from the vending operator to the food manufacturer. The FDA does not provide any analysis of the impact of this burden on food manufacturers.

- The discussion of costs to vending machine operators in the notice hinges critically on the assumption that product manufacturers will undertake the production of appropriate labeling and that the costs of displaying these labels to operators will therefore be minimal. Because the argument that costs to operators relies so heavily on the assumption that food product manufacturers will incur the necessary machine labeling costs, the FDA should provide clear and decisive evidence that this will indeed be the case. Whether small operators will have to find space on their machines to display supplied label stickers and apply them, or whether they will be fully responsible for labeling if manufacturers do not supply the labels, they will face compliance burdens. FDA should document these burdens and then make a determination under the RFA if they are significant or not.

(4) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

- NAMA believes that preferred option for nutritional labeling disclose would be if the FDA would allow front-of-pack labeling. Section 4205 of the PPACA allows for the listing of caloric information if the prospective purchaser is able to examine the Nutritional Facts Panel before purchasing the article, or visible nutrition information is otherwise provided at the point of purchase. Providing

[6] Id.

affected businesses with maximum flexibility and solutions will serve to minimize any impacts associated with the rulemaking.

- Advocacy was told that if the FDA accepts NAMA's previously submitted proposal on nutritional labeling (the posting of one menu with calorie counts of all foods which are stocked in a bank of vending machines) the cost of the regulation may be reduced.

- As Congress recognized in framing PPACA section 4205, restaurants will need regulatory flexibility and a significant period of time for menu labeling implementation due to the nature of hand-preparation of restaurant foods, physical and logistical issues associated with menu and menu board changes, determinations of nutrient content, and training of personnel.

- FDA's Draft Guidance[7] requires that calorie disclosure be provided in the same type size as the name or price of a menu item (whichever is larger) and with the same color and contrasting background as the menu item. There are myriad ways a restaurant may provide calorie information in a manner that is clearly readable and easily understandable by the consumer, without being forced to comply with requirements governing font size, color, contrasting backgrounds, etc. The adoption of a flexible standard will better accomplish the statutory mandate that information be "clear and conspicuous" and will help keep down costs of menu redesign and training.

- The restaurant industry maintains that it is in a difficult position to provide the FDA with data on the agency's cost assumptions until the FDA provides industry with a clearer understanding of its intentions for the nutritional labeling rule.

- The RA believes that the language in the PPRACA provides legislative intent that congress meant that the entire law should be implemented through the rulemaking process. The FDA's approach outlined in the draft guidance document is burdensome and costly. The RA suggests that because of the complexities of this issue and the enormous costs involved, the FDA should proceed through regulation and not through the issuance of a number of guidance documents for industry.

- NAMA and the RA request that the FDA at minimum allow two years for any menu labeling regulations to be implemented. Providing the affected industries with sufficient time is fully consistent with how FDA has regulated labeling on packaged food.

[7] In August 2010 the FDA released a guidance document titled: Guidance for Industry: Questions and Answers Regarding the Effect of Section 4205 of the Patient Protection and Affordable Care Act of 2010 on state and Local Menu and Vending Machine Labeling Laws.

Conclusion

Advocacy requests that the FDA take the industries' comments into consideration as they create the regulatory framework for any parallel review process. Also, in light of the economic impact data provided by the industry and the FDA in the Notice, Advocacy encourages the FDA to comply with the RFA's requirement that it analyze any impacts associated with any regulation and to entertain any reasonable alternatives that will serve to minimize those impacts. 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.

Sincerely yours,

Winslow Sargeant, Ph.D.
Chief Counsel for Advocacy

Linwood L. Rayford, III
Assistant Chief Counsel Advocacy

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