

**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**

**0910-0665**

**SUPPORTING STATEMENT**

**A. Justification**

1. Circumstances Making the Collection of Information Necessary

On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act ("Affordable Care Act") (P.L. 111-148). Section 4205 of the legislation, which principally amends sections 403 and 403A of the Federal Food, Drug, and Cosmetic Act (the act), 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 (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. Section 4205 preempts State and local governments from establishing menu labeling requirements for chain retail food establishments and vending machine nutrition labeling requirements that are not "identical to" the section 4205 requirements.

Section 4205 became effective on the date the law was signed, March 23, 2010. The provisions that went into immediate effect are as follows:

For chain retail food establishments:

- Disclosing the number of calories in each standard menu item on menus and menu boards,
- Making additional written nutrition information available to consumers upon request,
- Providing a statement on menus and menu boards about the availability of the written nutrition information, and
- Providing calorie information (per serving or per food item) for self-service items and food on display, in a sign adjacent to each food item.

For chain vending machine operators:

- Providing a sign in close proximity to each article of food (or the selection button) that discloses the number of calories contained in the article, unless a prospective purchaser is able to examine the Nutrition Facts Panel before purchasing the article, or visible nutrition information is otherwise provided at the point of purchase.

Section 4205 of the legislation requires record keeping – for the calorie analysis – and a third party disclosure – for the menu and vending machine labeling.

In the FEDERAL REGISTER of August 25, 2010 (75 FR 52427), FDA published a Notice of Availability of the guidance document entitled "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.” The guidance is intended to clarify section 4205’s effect on State and local menu and vending machine labeling laws, and to ensure that industry and State and local government understand the immediate effects of the law. Persons with access to the Internet may obtain the guidance at the following website:  
<http://www.cfsan.fda.gov/~dms/guidance.html>.

FDA published a second Notice of Availability in the FEDERAL REGISTER of August 25, 2010 (75 FR 52426), announcing the availability of a draft guidance document entitled “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.” On January 25, 2011 (76 FR 4360), FDA announced the withdrawal of this draft guidance and its intention to complete the notice-and-comment rulemaking process for section 4205 before initiating enforcement activities based, in part, on extensive comments on the draft guidance submitted to the Agency.

FDA is requesting OMB approval of the information collection provisions in the guidance 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,” and the Recordkeeping and Mandatory Third Party Disclosure provisions of section 4205.

2. Purpose and Use of the Information Collection

Menu and vending machine labeling will be used by consumers to assess the calorie content of their purchases. The purpose of the disclosure is to allow consumers to choose foods that are appropriate for their energy needs. Because consumers do not observe the preparation of food prepared by restaurants or similar retail food establishments, and because many of these foods were exempted from nutrition labeling requirements under the National Labeling Education Act (NLEA), consumers were not able to ascertain the calorie content of this food, and therefore could not make informed decisions about how that food fits their calorie requirements without the disclosure. The calorie information will be collected and recorded by the chain retail food establishments and chain vending machine operators that are required to disclose calorie information to their customers. The covered entities will use the records to ensure that calorie information that they disclose is accurate.

Description of Respondents: Respondents to this collection of information include food service retailers and vending machine operators (businesses and nonprofits in the private sector).

3. Use of Improved Information Technology and Burden Reduction

The legislation specifies that the calorie information be presented on menus, menu boards and food displays. Respondents may use any available information technology to develop their menus, menu boards and food displays. However, there is currently no information technology that establishments can use as a substitute for conventional

menus, menu boards and food displays to deliver the necessary information to consumers. FDA expects most of the disclosures to be made on printed materials. Thus, FDA estimates that none of the respondents (0%) will use electronic means to fulfill the nutrition labeling requirements of the legislation.

Companies are free to use whatever forms of information technology may best assist them in retaining the appropriate records for the calorie analysis. FDA estimates that all of the respondents (100%) will use electronic means for recordkeeping.

4. Efforts to Identify Duplication and Use of Similar Information

There is no duplication of nutrition labeling requirements by State or local or other federal agencies. The FDA is the only Federal agency that requires the specified information to appear on menus and food displays. As noted above, State and local governments cannot directly or indirectly impose any nutrition labeling requirements for chain restaurants or similar retail food establishments or vending machines that are not “identical to” the section 4205 requirements. To the extent that firms have already collected and recorded calorie information on their products, this legislation does not require additional recordkeeping.

5. Impact on Small Businesses or Other Small Entities

With regard to retail food establishments, FDA currently estimates that no small businesses (0%) will be covered by the legislation. The legislation only applies to restaurants or similar retail food establishments with 20 or more outlets, and to vending machine operators controlling at least 20 machines. In the case of retail food establishments, FDA believes very few, if any, of the covered firms are small businesses. The Small Business Administration (SBA) defines a small firm operating under NAICS three digit code 722 – Food Services and Drinking Places – as one with less than \$7 million in annual revenue. FDA estimates that all of the restaurant or similar retail food establishments that FDA has identified as being covered have revenue in excess of this limit.

In terms of vending machine operators, FDA estimates that approximately 93% of all vending machine operators, or approximately 4,900 operators, are small businesses and are covered by the legislation. For vending machine operators, NAICS 454200, the SBA also defines small businesses as those with annual revenue less than \$7 million. Because almost all vending machines deliver food that is covered by NLEA, these firms will not have to pay for calorie analysis. To the extent that calorie information is not visible to the consumer before purchase on the package, these firms will need to disclose calorie information. However, the burden for vending machine operators is proportional to the number of machines operated, so that the burden on small businesses will be less.

FDA is requiring the minimum collection of information and disclosure of information that is consistent with the legislation and its directives to FDA. FDA aids small businesses in complying with nutrition labeling requirements through the agency’s Regional Small Business Representatives and through the administrative and scientific

staffs within the Agency. FDA has provided a Small Business Guide on the agency's website at <http://www.fda.gov/oc/industry/>.

6. Consequences of Collecting the Information Less Frequently

Once new menus and displays are in place, respondents will update the nutrition labeling information on an occasional basis, e.g., with certain changes in the composition of menu items or the addition of new menu items, to the extent required by the PPACA.

If information is collected less frequently, or if disclosure is not continuous, then firms will be out of compliance with the legislation. In this case, consumers would be unable to make informed choices about the nutritional content of the food they purchase.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), in the FEDERAL REGISTER of November 5, 2010 (75 FR 68361), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received twenty letters in response to the notice, each containing one or more comments.

(Comment 1) FDA received several comments on the utility of the vending machine labeling provisions of section 4205 of the Affordable Care Act (ACA). Some comments argued that the ACA's vending machine labeling provisions have very little utility because the consumer is already familiar with the calorie content of vending machine products. Other comments stated that vending machine labeling would be useful to the consumer because grouping items in vending machines into categories (e.g., beverages, chips, gums) on a menu would help consumers select items by comparing similar items.

(Response) As noted previously, section 4205 of the Affordable Care Act amends Section 403(q) of the Federal Food, Drug, and Cosmetic Act (FFDCA) to, among other things, require vending machine operators that own or operate 20 or more vending machines to disclose nutrient content for certain food articles sold from vending machines; thus, this requirement is imposed by the law itself. Congress required FDA to publish a proposed rule by March 23, 2011, explaining how it will implement the law. Comments such as these on the utility of the provisions of the law are being considered by FDA in developing the proposed rules. FDA will also accept comments on the proposed rules and will consider them fully in developing final rules.

(Comment 2) Several comments suggested ways in which the burden of disclosing calorie content of vending machine products could be lessened. One comment suggested that vendors be permitted to post a sheet or menu on vending machines that lists the caloric contents of all their products. Another comment proposed electronic posting of calorie information, similar to the way that some vending machines post prices (the consumer looks it up by pressing the item number before making a purchase). Several

other comments suggested ways in which the burden of disclosing calorie content on restaurant menus could be lessened. For example, comments suggested that restaurants be allowed flexibility with menu labeling because of the many types of menus and menu boards, citing the need for different menus for full service vs. quick service, drive-through service, carryout orders, and self-service food or buffets. Suggestions for flexibility included permitting the calorie disclosures on handouts or placards; permitting disclosures to be brief, only required on one page of the menu or one panel of the menu board, and combined with other required statements and disclosures; permitting calorie disclosure for self-service beverages on the menu board as opposed to at the beverage fountain; and permitting a standard per ounce calorie disclosure for standardized beverages such as coffee and orange juice.

(Response) The requirement that affected chain retail food establishments and vending machine operators disclose certain nutrition information for certain food items offered for sale is imposed by Section 4205 of the ACA. Comments such as these on minimizing the burden of the law are being considered by FDA in developing the proposed rules. FDA will also accept comments on the proposed rules and will consider them fully in developing final rules.

(Comment 3) Several comments argued that FDA underestimated the burden hours and costs associated with complying with the provisions of section 4205 of the ACA. Several comments argued that the annual burden hours will be higher than FDA's estimate. One comment argued that FDA did not fully consider the time needed to acquire the required nutrition information. One comment suggested that FDA provide estimated burden hours individualized for each industry (i.e., convenience stores, restaurants, and grocery stores). Some comments argued that FDA underestimated the number of affected businesses in the United States and their rate of growth. Other comments argued that the percentages of the industries that will be impacted will be higher.

(Response) FDA appreciates the data and suggestions provided in the comments. However, the agency stands by its preliminary estimate of the paperwork burden resulting from section 4205 of the ACA. Thus, FDA has not changed the burden hour estimates in tables 1 and 2 of this document. This rough estimate of 14 million recurring hours in annual burden was a preliminary figure designed to cover a range of possible, non-specific requirements. During the upcoming rulemaking process, FDA seeks to minimize the regulatory burden on small businesses, and we anticipate the actual burden may differ from the preliminary estimate, depending upon the specific requirements that will be laid out in the final rules.

(Comment 4) Several comments had suggestions for the upcoming rulemaking.

(Response) FDA appreciates the information provided in the comments and will consider them in the upcoming rulemakings.

(Comment 5) One comment identified our inadvertent omission of the capital costs column in Table 2 of the November 5, 2010 notice.

(Response) We have corrected the table in the 30-day notice by inserting the missing capital costs column for comment.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any gifts or payments to respondents.

10. Assurance of Confidentiality Provided to Respondents

None of the nutrition information required to appear on the menus and food displays is confidential.

11. Justification for Sensitive Questions

This information does not contain questions pertaining to sexual behavior and attitudes, religious beliefs, or any other matter commonly considered private or of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

FDA estimates the burden of this collection of information as follows. The burden is described below in two parts: a recordkeeping burden associated with discovering and recording the calorie count for each menu/vending item; and the third party disclosure burden associated with communicating that information to the consumer. The estimates are also separated for retail food service and vending operators.

12 a. Annualized Hour Burden Estimate

FDA estimates a total of 1,388,010 initial burden hours. This number has been divided by three in the tables below in order to annualize the burden hours over a 3 year period, yielding 141,222 initial hours for recordkeeping and 312,448 initial hours for third party disclosure, for a sum of 462,670 initial hours. FDA estimates a total of 14,068,808 recurring hours, with nearly all of these for vending machine operators, including 31,408 recurring hours for recordkeeping and 14,037,400 recurring hours for third party disclosure.

Recordkeeping burdens for chain retail food establishments

The time burden for calorie analysis on chain retail food establishments is the time necessary for creating a record, managing the contracts for analysis, and communicating the results of the analysis to the outlets. FDA estimates the hourly burden of calorie analysis on these firms to be 4 hours per menu item.

FDA estimates that there are approximately 1,069 restaurant chains, with 231,000 outlets, will be required to disclose calorie information. On average, we estimate that a chain has 117 items on its menu, and that 48% of chain restaurants, or 516, do not already have calorie information. The hourly burden for restaurant chains is 241,488 hours (=516 chains x 117 items/chain x 4 hours/item). The analogous number displayed in the first row of Table 1, 80,496, is a result of dividing by three the burdens that occur only in the first year, to avoid double counting in the ROCIS system.

This burden estimate for restaurants increased from 99,760 hours to 241,488 hours because the estimate of covered restaurants rose from 500 to 1,069 and because the number of estimated items per menu rose from 116 to 117, due to better data.

FDA estimates that there are 570 covered grocery and convenience store chains with an average of 40 standard menu items per chain. The hourly burden for grocery store chains is 91,200 hours (=570 chains x 40 items/chain x 4 hours/item). The analogous number displayed in the second row of Table 1, 30,400, is a result of dividing by three the burdens that occur only in the first year, to avoid double counting in the ROCIS system.

The burden estimate for grocery and convenience stores rose from 84,000 hours (total grocery and convenience) to 91,200 hours because the number of estimated grocery stores chains fell from 150 to 120, and the number of estimated convenience stores rose from 200 to 450. The number of estimated items per chain fell from 100 for groceries and rose from 30 for convenience stores to 40 for all of these stores. All of these changes were due to better data.

FDA estimates that there are 420 other chains that will be covered by the proposed rule. With 40 menu items on average, the number of hours required to deal with calorie analysis at these other chains is 67,200 hours (=420 chains x 40 items/chain x 4 hours/item). The analogous number displayed in the third row of Table 1, 22,400, is a result of dividing by three the burdens that occur only in the first year, to avoid double counting in the ROCIS system.

The burden estimate for other chains fell from 85,000 hours to 67,200 hours because the estimated number of recordkeepers fell from 450 to 420, and the number of estimated items per chain fell from 50 to 40. Both changes were due to better data.

FDA has estimated that each of the 1,506 covered chains, on average, introduces new items or reformulates existing items 4 times per year. The recurring hourly burden of recordkeeping for new items, as displayed in the sixth row of Table 1, is 24,096 hours (=1,506 chains x 4 items/chain x 4 hours/item).

The recurring burden estimate for new items rose from 20,400 to 24,096 because the total number of estimated covered chains rose from 1,275 to 1,506. This change was from the changes detailed above.

FDA estimates that 30 chains will become newly covered under the requirements of the proposed rule each year. With an average number of menu items of 60 per chain, this would result in approximately 7,200 hours (=30 chains x 60 items/chain x 4 hours/item).

Because both the estimated number of covered chains changed as above, and the estimated rate of growth changed from .5 to 2 percent, the estimated number of changes increased from 6 to 30. The estimated number of items per chain fell from 80 to 60, due

to changes in the number of chains in each sector, and the changes in the number of items in each sector. These changes resulted in the burden rising from 1,920 to 7,200.

FDA has estimated that the average cost of acquiring a full nutrition analysis is \$269 per menu item. These costs are calculated by multiplying this per item cost by the number of items multiplied by the number of recordkeepers, except for vendors, the calculation of which is described below.

Table 1: Estimated Annual Recordkeeping Burden: Calorie analysis and recording<sup>1</sup>

| Type of Respondent                   | No. of Recordkeepers | Annual Frequency per Recordkeeper | Total Annual Records | Hours per Record | Total Hours | Total Capital Costs |
|--------------------------------------|----------------------|-----------------------------------|----------------------|------------------|-------------|---------------------|
| Restaurant chains                    | 172                  | 117                               | 20,124               | 4                | 80,496      | \$5,413,356         |
| Grocery and Convenience Store chains | 190                  | 40                                | 7,600                | 4                | 30,400      | \$2,044,400         |
| Other chains                         | 140                  | 40                                | 5,600                | 4                | 22,400      | \$1,506,400         |
| Vending operators                    | 200                  | 20                                | 4,000                | 2                | 8,000       | \$17,933            |
| Total annual hours                   |                      |                                   |                      |                  | 141,296     | \$8.982089          |
| New/Reformulated items               | 1,506                | 4                                 | 6,024                | 4                | 24,096      | \$1,620,456         |
| New chains                           | 30                   | 60                                | 1,800                | 4                | 7,200       | \$484,200           |
| New vendors                          | 3                    | 20                                | 60                   | 2                | 120         | \$4000              |
| Total recurring hours                |                      |                                   |                      |                  | 31,416      | \$12,160,952        |

<sup>1</sup>No. of recordkeepers, total hours, and total capital costs have been divided by 3 to avoid double counting in the ROCIS system. There are no operating and maintenance costs associated with this collection of information.

### Third party disclosure burdens for chain retail food establishments

The third party reporting burden for chain retail food establishments is the time necessary to display calorie information on menus, menu boards, displayed food and other required locations. In practice, this is the time necessary to change out redesigned menu boards, FDA estimates two hours of time per menu board change.

Estimates in this section have changed since the previous estimate because the method for estimating burden has changed. In the previous analysis, the unit of disclosure was the menu item, in this analysis the unit of measure is the menu or menu board. This



change more closely ties the burden estimates to the capital costs and better reflects how businesses will accrue costs associated with third party disclosure.

FDA estimates that limited service restaurant chains have an average of 3 menu boards or displays per establishment. With 135,705 outlets having these displays, the total hourly burden estimated for third party disclosure at restaurants is 814,230 hours (=135,705 outlets x 3 displays/outlet x 2 hours/display). The analogous number displayed in the first row of Table 2, 271,410, is a result of dividing by three the burdens that occur only in the first year, to avoid double counting in the ROCIS system.

This burden estimate for restaurants increased from 730,800 hours to 814,230 hours because of the method change noted. In addition, the number of establishments fell from 210,000 to 135,705 due to better data.

For grocery and convenience store chains, FDA estimates an average of one major menu board or display per establishment. With 41,945 outlets, the total hourly burden is 83,890 hours (=41,945 outlets x 1 displays/outlet x 2 hours/display). The analogous number displayed in the second row of Table 2, 27,963, is a result of dividing by three the burdens that occur only in the first year, to avoid double counting in the ROCIS system.

This burden estimate has changed from a total, combined estimate of 19,667 hours to 83,980 hours. In addition to the method change, the estimated number of establishments changed from 95,000 to 41,945. This decrease is due to better data.

For other covered chains, FDA estimates 33,114 covered outlets, each with an average of one major display or menu board. At 4 hours per disclosure, FDA estimates an hourly burden of 66,228 hours (=33,114 outlets x 1 displays/outlet x 2 hours/display). The analogous number displayed in the third row of Table 2, 22,076, is a result of dividing by three the burdens that occur only in the first year, to avoid double counting in the ROCIS system.

This burden estimate has changed from 170,000 hours to 66,228 hours. In addition to the methods change, the estimated number of establishments fell from 170,000 to 33,114.

#### Recurring disclosure burdens for chain retail food establishments

FDA estimates that the annual number of newly covered chains will be 30. At 20 establishments per chain, there will be 600 establishments at newly covered chains each year that will need to disclose calorie content. Taking an average number of displays equal to 2, the total hourly burden for disclosure due to newly covered chains is 2,400 hours (=600 outlets x 2 displays/outlet x 2 hours/display).

As with the recordkeeping burden, the estimate of the number of newly covered chains changed because the rate of growth changed from .5 to 2 percent, and the total estimate of the number of covered chains changed. However, the methods change drove the estimated burden down. Therefore, the estimated burden here fell from 5,961 hours to

2,400 hours. Note that the previous estimate have 57,000 hours burden from updating disclosures due to new items. However, the burden of updating menus would occur in the absence of this disclosure requirement. Therefore, that estimated burden should not have been included.

The final column of Table 2 gives the estimated capital costs associated with third party disclosure. These are the costs of acquiring new menu boards or displays. FDA has estimated that the average cost of menu board to be \$550. These costs are calculated by multiplying this per menu board cost by the frequency of disclosures in column three multiplied by the number of respondents in column two.

The estimated capital cost for “Other chains” decreased from \$22 million to \$18.2 million because of an arithmetic error. This correcting this error caused the Total initial capital costs to fall from \$269.1 million to \$265.3 million. A rounding error in the capital costs for “New SRFE outlets” led to an increase in estimated costs from \$0.6 million to \$0.7 million. Correcting this error led to an increase in the Total recurring capital costs of \$0.1 million, to \$3.5 million.

Table 2. -- Estimated Annual Third Party Disclosure Burden: Calorie Content<sup>1</sup>

| Type of Respondent                   | No. of Respondents | Annual Frequency Per Disclosure | Total Annual Disclosures | Hours per Disclosure | Total Hours | Total Capital Costs |
|--------------------------------------|--------------------|---------------------------------|--------------------------|----------------------|-------------|---------------------|
| Restaurants                          | 45,235             | 3                               | 135,705                  | 2                    | 271,410     | \$74,637,750        |
| Grocery and Convenience Store chains | 13,982             | 1                               | 13,982                   | 2                    | 27,963      | \$7,689,917         |
| Other chains                         | 11,038             | 1                               | 11,038                   | 2                    | 22,076      | \$6,070,900         |
| Total initial hours                  |                    |                                 |                          |                      | 964,348     | \$88,398,567        |
| New SRFE outlets                     | 600                | 2                               | 1,200                    | 2                    | 2,400       | \$660,000           |
| Vending (ongoing)                    | 5,000              | 56,000                          | 280,000,000              | 0.05                 | 14,000,000  | \$2.8 million       |
| Vending (growth)                     | 5,000              | 140                             | 700,000                  | 0.05                 | 35,000      | \$7,000             |
| Total recurring hours                |                    |                                 |                          |                      | 14,037,400  | \$3,467,000         |

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|--|--|--|
|  |  |  |
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<sup>1</sup>No. of respondents, total hours, and total capital costs have been divided by 3 to avoid double counting in the ROCIS system. There are no operating and maintenance costs associated with this collection of information.

### Burdens for chain vending machine operators

Because almost 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 the operator level. Furthermore, most vended foods are subject to NLEA, which means that calorie content is already collected. A likely scenario for response to vending machine labeling is that food manufacturers include a set of calorie label stickers in each case of product. This would be efficient both because most manufacturers will already have the calorie information available, and because economies of scale exist for the manufacturer. In this case, vending machine operators will not need to keep a record of calorie content. Instead, the burden for most operators will be limited to that of administering records and passing the existing information on to consumers.

FDA estimates that there are approximately 300,000 beverage machines that sell unpackaged products. The manufacturer of the ingredients to these foods (hot coffee drinks and sodas) would not necessarily have calorie information if the products were not subject to NLEA in some form. There are likely a limited number of manufacturers of the inputs to the beverage machines. For the purposes of this document, FDA estimates that there are 10 manufacturers serving these machines, and 20 drinks per manufacturer, so that approximately 200 drinks would need to have calorie analysis. The cost of this calorie analysis will be included in the capital costs below. FDA estimates that the record keeping burden for these firms is half that for restaurants, or two hours per item. If there are 600 firms using beverage dispensers, then the hourly burden for recordkeeping is 24,000 hours (=600 firms x 20 items/firm x 2 hours/item).

FDA believes that the set of items sold in these dispensary machines is approximately constant. If there is .5 percent growth in the number of firms, then approximately three new firms will become covered in this market in a given year. The burden associated with these three firms would be 120 hours (=3 firms x 20 items/firm x 2 hours/item). This amount is given in eighth row of Table 1.

The third party reporting for chain vending machine operators is the time necessary to install calorie displays on their vending machines. Because there is wide variation in the kinds of vending machines used – in materials, display, mechanism– there likely be a variety of solutions. On the high end, a calorie display that is integrated with the graphics on the machine may cost several hundred dollars or more. On the low end, a set of calorie stickers affixed to the front of the machine would cost at most a few dollars per machine. Given the low margins in the vending machine industry, and given that nearly all of the regulated operators will be small businesses, FDA believes that almost all operators will, at least initially, choose the sticker option. Because stickers do not require

any initial investment and because they are not durable, all burden and costs will be on a recurring basis. In the long run, the manufacturers of vending machines, and the larger vending machine operators, such as the soft drink companies, may use the more integrated, and thus expensive, solution.

FDA tentatively estimates a recurring hourly burden of 1 hour per machine, 2 times per year to install the displays. If there are an average of 20 items per machine, then the burden per response is .05 hours (=1 hours/machine / 20 items/machine). This will be the time necessary to decide where to put the displays on the machine, and to sort, remove and affix calorie stickers. FDA expects the stickers to have a relatively short life, and the mix of product in a machine to change over time.

FDA estimates approximately 7 million machines are serviced by 5,000 operators, for an average number of machines per operator of 1,400 machines. If each machine has 20 items, then the average number of responses per operator is 28,000. Given that stickers will likely need to be replaced twice per year on average, this number of responses doubles, to 56,000 responses per operator. The total recurring hours needed for third party display is then 14 million hours (=5000 firms x 1,400 machines/firm x 20 displays/machine x .05 hours/display x 2). This amount is recurring in every year, and is given in row 7 of Table 2.

If growth in the vending machine industry is .5 percent, then each of the 5,000 respondents will have an average of 7 additional machines that would need to report calorie content each year. With an average number of items per machine of 20, the number of disclosures per respondent is 140. At .05 hours per response, the hours needed to disclose calorie content on new machines is 35,000 hours per year (=5000 firms x 7 machines/firm x 20 items/machine x .05 hours/item). This amount is displayed in row 8 of Table 2.

12b. Annualized Cost Burden Estimate

Hourly burdens are taken from the last columns of Tables 1 and 2 above. We use average hourly wage rates from the Bureau of Labor Statistics May 2009 Industry-Specific Occupational data “All Occupations” category to reflect the variety of labor types that will be necessary for these burdens. For restaurants and other, we use NAICS 722 data. For grocery and convenience stores we use NAICS 445 data. Vending operator wages are given from NAICS 454200. Recurring wage rates are averages. These estimates have changed due to changes detailed in the hourly burden analysis.

| Table 3. – Estimated Costs of Hourly Burden |                              |                  |                                     |                  |                        |
|---|------------------------------|------------------|-------------------------------------|------------------|------------------------|
| Type of Respondent                          | Total Hours (record-keeping) | Hourly Wage Rate | Total Hours (Third party reporting) | Hourly Wage Rate | Total Respondent Costs |
|   |                              |                  |                                     |                  |                        |

|                                      |        |         |            |         |                |
|--------------------------------------|--------|---------|------------|---------|----------------|
| Restaurant chains                    | 80,496 | \$10.13 | 271,410    | \$10.13 | \$3,564,808    |
| Grocery and Convenience Store chains | 30,400 | \$12.06 | 27,963     | \$12.06 | \$703,862      |
| Other chains                         | 22,400 | \$10.13 | 22,076     | \$10.13 | \$450,542      |
| Vending operators                    | 8,000  | \$15.27 | -2         | -2      | \$122,164      |
| Total initial hourly costs           |        |         |            |         | \$4,841,375    |
| New menu items                       | 24,096 | \$11.09 | 0          | \$11.09 | \$29.0 million |
| New SRFE firms                       | 7,200  | \$11.09 | 2,400      | \$11.09 | \$267,225      |
| Vending (ongoing)                    | 0      | \$15.27 | 14,000,000 | \$15.27 | \$213,780,000  |
| Vending (growth)                     | 120    | \$15.27 | 35,000     | \$15.27 | 536,282        |
| Total recurring hourly costs         |        |         |            |         | \$214,689,971  |

<sup>2</sup>The most inexpensive technology available to vending machine operators for disclosing calorie content is using stickers. Because these do not require any initial investment and because they are not durable, all burden and costs will be on a recurring basis.

### 13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

Cost estimates in this section are for capital costs. There are no maintenance or operating costs associated with this action other than the recurring hourly burdens given above. These cost estimates have changed because of the changes detailed in estimating the burden hours.

Because the firms are conducting analysis for the purpose of disclosure, the cost of analysis is PRA-relevant. FDA has estimated that the average cost of a full analysis is \$269 per menu item.

FDA estimates that 1,069 restaurant chains will be required to disclose calorie information. On average, we estimate that a chain has 117 items on its menu, and that 48% of chain restaurants, 516, do not already have calorie information published. The recordkeeping capital costs are equal to the cost of purchasing calorie analysis for all menu items not already analyzed. This is equal to the number of chains multiplied by the number of menu items multiplied by the cost of analysis per item: \$16.2 million (=516 chains x 117 items/chain x \$269/item).

The capital costs for calorie analysis by grocery and convenience stores are \$6.1 million (=570 chains x 40 items x \$269 item). The capital costs for other covered chains is estimated to be \$4.5 million (=420 chains x 40 items/chain x \$269/item).

Recurring capital costs of recordkeeping are the costs of analyzing new menu items. As above, we use 4 new items per year per firm on average. The capital costs of new items will be \$510,000 (=1,506 chains x 4 items/chain x \$269 item). The recordkeeping capital costs of entering firms will be \$0.5 million (=30 chains x 60 items/chain x \$269/item). This is the cost of an average new firm analyzing its entire set of menu items, multiplied by the number of new firms.

FDA estimates restaurant establishments have an average of three signs/menus that will need to be updated, so that disclosure capital costs will be \$224 million (210,000 restaurants x 3 displays x \$200/display).

Grocery and convenience stores tend not to have multiple displays featuring the same foods. For the purposes of this document FDA takes the number of menu displays to be 1. The capital costs associated with display are then \$23.1million (=41,945 outlets x 1 display x \$550/display)

The estimate for other similar retail food establishments takes the same number of displays, yielding \$18.2 million (=33,114 outlets x 1 displays/outlet x \$550/display).

The cost to newly covered firms will \$.7 million (=600 outlets x 2 displays/outlet x \$550/display).

The legislation also requires that SRFE make available written information with the required nutrition disclosures. For the purposes of this estimate, there are 177,650 covered establishments. If each of these establishments distributed 10 written nutrition information documents per month on average, then the yearly recurring number would be 21.3 million documents. At an estimated price of \$0.20 per document, the yearly cost would be \$4.2 million.

Annualized costs are given for firms updating menus and calorie analysis every three years.

| Type of Respondent                   | Initial Recordkeeping Capital Costs | Annualized Recordkeeping Capital Costs | Initial Third Party Reporting Capital Costs | Annualized Third Party Reporting Capital Costs |
|--------------------------------------|-------------------------------------|--|---|--|
| Restaurant chains                    | \$16.2 million                      | \$5.4 million                          | \$224.0 million                             | \$74.7 million                                 |
| Grocery and Convenience Store chains | \$6.1 million                       | \$2.0 million                          | \$23.1 million                              | \$7.7 million                                  |
| Other chains                         | \$4.5 million                       | \$1.5 million                          | \$18.2 million                              | \$6.1 million                                  |

|                                |                |                |                 |                |
|--------------------------------|----------------|----------------|-----------------|----------------|
| Vendors                        | \$20,000       | \$6,667        | \$0             | \$0            |
| Total Initial Capital Costs    | \$26.8 million | \$8.9 million  | \$265.3 million | \$88.4 million |
| Recurring Costs                |                |                |                 |                |
| New items                      |                | \$1.6 million  |                 | \$0.0 million  |
| New outlets                    |                | \$0.5 million  |                 | \$0.6 million  |
| Nutrition Handouts             |                |                |                 | \$4.2 million  |
| Vending ongoing                |                | \$4,000        |                 | \$2.8 million  |
| New machines                   |                | \$0            |                 | \$7,000        |
| Recurring capital costs        |                | \$2.1 million  |                 | \$0.6 million  |
| Total Annualized Capital Costs |                | \$11.0 million |                 | \$89.0 million |

<sup>1</sup>The most inexpensive technology available to vending machine operators for disclosing calorie content is using stickers. Because these do not require any initial investment and because they are not durable, all burden and costs will be on a recurring basis.

### Vending Machines

The costs of calorie analysis, the recordkeeping costs, for vending machine operators will be limited to those products that are not subject to NLEA. As above, FDA expects approximately 200 products will need calorie analysis. The initial capital costs of calorie analysis are then \$20,000 (=200 items x \$100/item).

The recurring third party reporting costs will be the costs of stickers displaying the calorie content of each item in a vending machine. With 7 million machines, an average of 20 items per machine, and, for the purposes of this document, 2 stickers per item per year, calorie display on vending machines will use 280,000,000 stickers. If stickers cost \$.01 each then the yearly capital cost of display will be \$2.8 million.

#### 14. Annualized Cost to the Federal Government

There are no costs to the Federal Government directly associated with this collection of information.

#### 15. Explanation for Program Changes or Adjustments

This is a revision request in which the estimated burden hours are being reduced by 4,621 hours due to the fact that FDA had better data to work with. As a result of FDA's deliberate action reducing the burden estimate, we recognize this as a revision (decrease) due to agency discretion. Also, we recognized a reduction in the number of responses as a result of this better data, i.e., a decrease of 37,914,854 responses.

We also made a correction in the cost estimates. An error was discovered and as a result, this ICR shows an adjustment increase in the cost estimate of \$51,418,746. The correction was made in the figures provided in ROCIS for Third Party Disclosure: Restaurant Chains – Calorie Content from \$52,500 to \$52,500,000 -- the correction generates an increase of \$52,447,500. However, comparing this ICR to the first ICR for the emergency submission, our cost estimates actually reduced by \$1,028,754 (the error of 52,447,500 – the change in ROCIS of 51,418,746 = 1,028,754). Thus, we are characterizing the reduction of \$1,028,754 as an adjustment.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans for tabulation or publication.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.