Dated: January 25, 2011.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2011–1998 Filed 1–28–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2011–N–0002]

Advisory Committees; Filing of Closed Meeting Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that, as required by the Federal Advisory Committee Act, the Agency has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2010.

ADDRESSES: Copies are available from the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 301–827–6860.

FOR FURTHER INFORMATION CONTACT: Teresa L. Hays, Committee Management Officer, Advisory Committee and Oversight Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5290, Silver Spring, MD 20993–0002, 301–796–8220.

SUPPLEMENTARY INFORMATION: Under section 10(d) of the Federal Advisory Committee Act (5 U.S.C. app.1) and 21 CFR 14.60(d), FDA has filed with the Library of Congress the annual reports for the following FDA advisory committees that held closed meetings during the period October 1, 2009, through September 30, 2010:

Center for Biologics Evaluation and Research:

Blood Products Advisory Committee,

Vaccines and Related Biological Products Advisory Committee.

National Center for Toxicological Research:

Science Board to the National Center for Toxicological Research.

Annual reports are available for public inspections between 9 a.m. and 4 p.m., Monday through Friday at the following locations:

1. The Library of Congress, Madison Bldg., Newspaper and Current Periodical Reading Room, 101 Independence Ave., SE., rm. 133, Washington, DC; and

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

Dated: January 26, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011–1992 Filed 1–28–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0567]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 2, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0665. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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—(OMB Control Number 0910–0665)—Revision

On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act of 2010 (“Affordable Care Act”) (Pub. L. 111–148). Section 4205 of the legislation, which principally amends sections 403 and 403A of the Federal Food, Drug, and Cosmetic Act (the FD&C 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 (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 of the Affordable Care Act 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 recordkeeping—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 Web site: *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." In the **Federal Register** of 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.

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 SRFE, 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 chain retail food establishments and chain vending machine operators.

In accordance with 5 CFR 1320.8(d), in the **Federal Register** of November 5, 2010 (75 FR 68361) (November 5, 2010 notice), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received 20 letters in response to the notice, each containing 1 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. Some comments argued that the Affordable Care Act'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 FD&C Act 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 rule 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 Affordable Care Act. Comments such as these on minimizing the burden of the law are being considered by FDA in developing the proposed rule. 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 Affordable Care Act. 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 Affordable Care Act. 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 this document by inserting the missing capital costs column for comment.

FDA estimates the burden of this collection of information as follows.

The burden is described in the following paragraphs 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. FDA estimates a total of 1,388,010 initial burden hours. This number has been divided by three in the following tables 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, that will be required to disclose calorie information. On average, we estimate that a chain has 117 items on its menu, and that 48 percent of chain restaurants, or 516, do not already have calorie information. The hourly burden for restaurant chains is 241,488 hours (= 516 chains × 117 items/chain × 4 hours/item).

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 × 40 items/chain × 4 hours/item).

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 × 40 items/chain × 4 hours/item).

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 of this document, is 24,096 hours (= 1,506 chains × 4 items/chain × 4 hours/item).

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 × 60 items/chain × 4 hours/item). This amount is displayed in the seventh row of table 1 of this document.

The final column of table 1 of this document gives the estimated capital costs associated with calorie and nutrition analysis. These are the costs of acquiring nutrition analyses. FDA has estimated that the average cost of a full analysis is $269 per menu item. These costs are calculated by multiplying this per item cost by the number of items in column three multiplied by the number of recordkeepers in column two.

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN: CALORIE ANALYSIS AND RECORDING [1]

Type of respondent	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours	Total capital costs
Restaurant chains	516	117	60,372	4	241,488	$16.2 million.
Grocery and Convenience Store chains.	570	40	22,800	4	91,200	$6.1 million.
Other chains	420	40	16,800	4	67,200	$4.5 million.
Vending operators	600	20	12,000	2	24,000	$20,000.
Total initial hours					423,888	$26.9 million.
New/Reformulated items	1,506	4	6,024	4	24,096	$1.6 million.
New chains	30	60	1,800	4	7,200	$0.5 million.
New vendors	3	20	60	2	120	$4,000.
Total recurring hours					31,416	$2.1 million.

[1] 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 2 hours of time per menu board change.

FDA estimates that limited service restaurant chains have an average of three 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 × 3 displays/outlet × 2 hours/display).

For grocery and convenience store chains, FDA estimates an average of 1 major menu board or display per establishment. With 41,945 outlets, the total hourly burden is 83,890 hours (= 41,945 outlets × 1 displays/outlet × 2 hours/display).

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 × 1 displays/outlet × 2 hours/display).

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 × 2 displays/outlet × 2 hours/display).

The final column of table 2 of this document 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. 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 [1]

Type of respondent	Number of respondents	Annual frequency of disclosure	Total annual disclosures	Hours per disclosure	Total hours	Total capital costs
Restaurants	135,705	3	407,115	2	814,230	$224 million.
Grocery and Convenience Store chains	41,945	1	41,945	2	83,890	$23.1 million.
Other chains	33,114	1	33,114	2	66,228	$18.2 million.
Total initial hours					964,348	$265.3 million.
New SRFE outlets	600	2	1,200	2	2,400	0.7 million.
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	$3.5 million.

[1] 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 recordkeeping 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 × 20 items/firm × 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 × 20 items/firm × 2 hours/item). This amount is given in the eighth row of table 1 of this document.

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 will 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, two 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 (= 5,000 firms × 1,400 machines/firm × 20 displays/machine × .05 hours/display × 2). This amount is recurring in every year, and is given in row 7 of table 2 of the document.

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 (= 5,000 firms × 7 machines/firm × 20 items/machine × .05 hours/item). This amount is displayed in row 8 of table 2 of this document.

Dated: January 25, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–1993 Filed 1–28–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0564]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Restaurant Menu and Vending Machine Labeling: Registration for Small Chains Under Section 4205 of the Patient Protection and Affordable Care Act of 2010

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 2, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0664. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

I. Background

Restaurant Menu and Vending Machine Labeling: Registration for Small Chains Under Section 4205 of the Patient Protection and Affordable Care Act of 2010—(OMB Control Number 0910–0664)—Revision.

On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) (Pub. L. 111–148). Section 4205 of the legislation, which principally amends sections 403 and 403A of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343 and 343–1, respectively), requires chain restaurants and similar retail food establishments (SRFE) with 20 or more locations, as well as operators of 20 or more vending machines, to disclose certain nutrition information on 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 in restaurants and calorie declarations for food in vending machines that are not "identical to" the section 4205 requirements.

In addition to restaurant menu and vending machine labeling, section 4205 of the Affordable Care Act provides that persons or firms not subject to the disclosure of nutrition information required by this legislation, such as restaurants with fewer than 20 locations or vending machine operators with fewer than 20 vending machines, may elect to be subject to the requirements provided in section 4205 by registering biannually with FDA. As required by section 4205, FDA published a notice in the **Federal Register** of July 23, 2010 (75 FR 43182) (the July 23, 2010, notice) to explain how retail food establishments and vending machine operators not otherwise subject to the provisions of section 4205 may voluntarily elect to become subject to them. The information collection requirements of FDA's program of voluntary registration under section 4205 of the Affordable Care Act were approved under OMB control number 0910–0664.

Voluntary registration allows companies with outlets or machines regulated by local or State calorie labeling requirements to opt instead for the requirements of section 4205 of the Affordable Care Act. The information provided to FDA will help Federal, State or local officials to determine which jurisdiction's requirements apply to the firm.

Description of Respondents: Respondents to this collection of information include retail food establishments and vending machine operators with fewer than 20 outlets or machines.

FDA's July 23, 2010, notice requires that retail food establishments and vending machine operators register with FDA using the Agency's Form FDA 3757 available at *http://www.fda.gov/menulabeling.* FDA prefers that the information be submitted by email by typing complete information into the form (PDF), saving it on the registrant's computer, and sending it by email to *http://menulawregistration@fda.hhs.gov.* If email is not available, the registrant can either fill in the form (PDF) and print it out (or print out the blank PDF and fill in the information by hand or typewriter), and send it to FDA either by faxing the completed form to 301–436–2804 or mailing it to the Center for Food Safety and Applied Nutrition, Compliance Information Branch (HFS–681), 5600 Fishers Lane, Rockville, MD 20857.

Information FDA requires on the registration form for restaurants and similar retail food establishments includes the following:

- The name, address, phone number, email address, and contact information for the authorized official;
- The name, address, and email address of each restaurant or similar retail food establishment being registered, as well as the name and contact information for an official onsite, such as the owner or manager, for each specific restaurant or similar retail food establishment;
- All trade names the restaurant or similar retail food establishment uses;
- Preferred mailing address (if different from location address for each establishment) for purposes of receiving correspondence; and
- Certification that the information submitted is true and accurate, that the person or firm submitting it is