is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products—Extension—Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Cigarette smoking is the leading preventable cause of premature death and disability in the United States. Each year, more than 440,000 premature deaths occur as the result of diseases related to cigarette smoking. The Centers for Disease Control and Prevention (CDC), Office on Smoking and Health (OSH) has the primary responsibility for the Department of Health and Human Services (HHS) smoking and health program. HHS's overall goal is to reduce death and disability resulting from cigarette smoking and other forms of tobacco use through programs of information, education and research.

The Comprehensive Smoking Education Act of 1984 (CSEA, 15 U.S.C. 1336 or Public Law 98–474) requires each person who manufactures, packages, or imports cigarettes to provide the Secretary of Health and Human Services (HHS) with a list of ingredients added to tobacco in the manufacture of cigarettes. The legislation also authorizes HHS to undertake research, and to report to the Congress (as deemed appropriate) discussing the health effects of these ingredients.

HHS has delegated responsibility for implementing the CSEA's ingredient reporting requirements to CDC's Office on Smoking and Health (OSH). OSH has collected ingredient reports on cigarette products since 1986. Respondents are commercial cigarette manufacturers, packagers, or importers, or their designated representatives. Respondents are not required to submit specific forms, however, they are required to submit a list of all ingredients used in their products. CDC requires the ingredient report to be submitted by chemical name and Chemical Abstract Service (CAS) Registration Number, consistent with accepted reporting practices for other companies currently required to report ingredients added to other consumer products. Typically, respondents submit a summary report to CDC with the ingredient information for multiple products, or a statement that there are no changes to their previously submitted ingredient report.

Ingredient reports for new products are due at the time of first importation. Thereafter, ingredient reports are due annually on March 31. Information is submitted to OSH by mailing a written report on the respondent's letterhead, by CD, three-inch floppy disk, or thumb drive. Electronic mail submissions are not accepted. Upon receipt and verification of the annual ingredient report, OSH issues a Certificate of Compliance to the respondent.

There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden hours
Cigarette Manufacturers, Packagers, and Importers	143	1	6.5	930

Dated: November 1, 2010.

Carol E. Walker,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–27983 Filed 11–4–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0567]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the recordkeeping and mandatory third party disclosure provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010 (ACA).

DATES: Submit either electronic or written comments on the collection of information by January 4, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the 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: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or

requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these 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.

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 ACA (Pub. L. 111–148). Section 4205 of the legislation, which principally amends sections 403 and 403A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343 and 343–1), requires chain restaurants and similar retail food establishments (SRFE) with 20 or more locations doing business under the same name and offering for sale substantially the same menu items (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 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.* In addition, the information collection requirements were approved under the emergency processing provisions of the PRA and assigned OMB control number 0910–0665.

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 chain retail food establishments and chain vending machine operators.

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 tables 1 and 2 of this document in order to avoid double counting in the Regulatory Information Service Center (RISC) and Office of Information and Regulatory Affairs (OIRA) Consolidated Information System to yield 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 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 1of 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.

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

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

Type of respondent	Number of recordkeepers	Annual frequency per recordkeeper	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	$0,000
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	

[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).

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.

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.

TABLE 2—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN: CALORIE CONTENT [1]

Type of respondent	Number of respondents	Annual frequency per disclosure	Total annual disclosures	Hours per disclosure	Total hours
Restaurants	135,705	3	407,115	2	814,230
Grocery and Convenience Store Chains	41,945	1	41,945	2	83,890

TABLE 2—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN: CALORIE CONTENT [1]—Continued

Type of respondent	Number of respondents	Annual frequency per disclosure	Total annual disclosures	Hours per disclosure	Total hours
Other Chains	33,114	1	33,114	2	66,228
Total Initial Hours					964,348
New SRFE Outlets	600	2	1,200	2	2,400
Vending (Ongoing)	5,000	56,000	280,000,000	0.05	14,000,000
Vending (Growth)	5,000	140	700,000	0.05	35,000
Total Recurring Hours					14,037,400

[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 in the following paragraphs. 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 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 will 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. 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 × 1,400 machines/firm x 20 displays/machine × .05 hours/display × 2). This amount is recurring in every year, and is given in row 7 of table 2 of this 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 (= 5000 firms × 7 machines/firm × 20 items/machine × .05 hours/item). This amount is displayed in row 8 of table 2 of this document.

Dated: November 1, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–28014 Filed 11–4–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0275]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Full-Field Digital Mammography System; Availability

AGENCY: Food and Drug Administration, HHS.