Restaurant Menu and Vending Machine Labeling: Registration for Small Chains Under Section 4205 of the Patient Protection and Affordable Care Act of 2010

0910-0664

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, 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.

   FDA is requesting OMB approval of the information collection provisions in the July, 23, 2010 notice and the Registration provisions of section 4205.

2. Purpose and Use of the Information Collection

   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.

   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 e-mail by typing complete information into the form (PDF), saving it on the registrant's computer, and sending it by e-mail 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 name, address, phone number, e-mail address, and contact information for the authorized official;
- The name, address, and e-mail 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 authorized to do so, and that each registered restaurant or similar retail food establishment will be subject to the requirements of section 4205.

Information FDA requires on the registration form for vending machine operators includes:

- The name, address, phone number, e-mail address, and contact information for the vending machine operator;
- The address of each vending machine owned or operated by the vending machine operator, and the name and contact information, including e-mail address, of the location in which each vending machine is located;
- Preferred mailing address (if different from location address), for purposes of receiving correspondence; and
- Certification that the information submitted is true and accurate, that the person or firm submitting it is authorized to do so, and that each registered restaurant or similar retail food establishment will be subject to the requirements of section 4205.

In addition to the initial registration, the authorized official must register every other year with FDA, and the registration will automatically expire if not renewed.

Description of Respondents: Respondents to this collection of information include food service retailers and vending machine operators (businesses and nonprofits in the private sector) with fewer than 20 outlets or machines.

3. Use of Improved Information Technology and Burden Reduction

Because of the short timeline, FDA is implementing an interim registration process consisting of a downloadable form that will indicate the required information and where to fax, send or email the completed document. FDA estimates that all of the respondents (100%) will electronic means for reporting under this interim process.

FDA will implement an online registration process that will allow firms to manage their registration information, and will minimize the burden by allowing firms to re-register by either changing only the details that have changed, or by certifying that no information has changed. FDA estimates that all of the respondents (100%) will use electronic means for reporting once the system is in place.

4. Efforts to Identify Duplication and Use of Similar Information

There are no existing data sources that indicate a small firm's choice as to whether they wish to be covered under existing local and state menu or vending labeling rules, or under Section 4205 of the act.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that no small businesses (0%) will be affected by the reporting. Currently applicable state or local menu labeling rules apply to chains with a minimum of 15 outlets. 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. From the limited data that FDA has been able to collect to date, SRFE chains with at least 15 outlets will have sales that exceed this limit. There are no current local or state vending machine labeling regulations. Therefore, FDA expects no small vending machine operators (0%) to be affected by the registration.

To the extent that a small business may be impacted, the registration process is specifically designed to minimize their regulatory burden by giving them a choice as to which rules they wish to follow. The registration process is voluntary, and is the minimum burden that the FDA can impose in order to give firms this choice and to give regulatory authorities the information they need to enforce the appropriate statutes.
If a small business chooses to register, FDA can aid 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

The act mandates a twice yearly registration. FDA has no authority to collect the information less frequently.

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 4, 2010 (75 FR 67978), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one letter in response to the notice, which contained multiple comments.

(Comments) One comment suggested that FDA underestimated the number of affected businesses in the United States, particularly with regard to the number of affected convenience stores, and their rate of growth. Another comment suggested that FDA provide estimated burden hours individualized for each industry (i.e., convenience stores, restaurants, and grocery stores).

(Response) FDA appreciates the data and suggestions provided in the comments and will consider them in the upcoming rulemakings. 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 estimates in table 1 of this document.

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

The information collected is limited to addresses and contact information for authorized individuals at firms volunteering to be covered under section 4205. The purpose of the information collection is to give regulatory authorities the information they need to enforce the appropriate statutes. Therefore, some or all of this information cannot be 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

12 a. Annualized Hour Burden Estimate

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

Table 1. -- Estimated Annual Reporting Burden[1]

Type of Respondent	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response (average)	Total Hours
Restaurant initial	103	1	103	2	206
Grocery initial	167	1	167	2	334

Convenience store initial	11	1	11	2	22
Other SRFE initial	81	1	81	2	162
Total initial hours					724
New registrations	7	1	7	1	7
Re-registrations	355	1	355	0.25	89
Total recurring hours					96
Total burden hours					820

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates the reporting burden of this information collection to be 724 hours in the first year and 96 hours each year thereafter. The registration burden will be an ongoing, semi-annual reporting of firm contact and location information to FDA. FDA bases its per respondent burden on the PRA analysis for section 415 of the FFDCA (21 U.S.C. 350d) as laid out for the rule "Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (Ref. 1). FDA estimates that the initial collection of the information, and presentation of it in a format that will meet the agency's registration regulations, will require a burden of approximately two hours per registration for the first year because the registration system will not be fully automated.

FDA estimates that renewal registrations after the first year will require substantially less time because firms are expected to be able to affirm or edit the existing information in an online account in a way similar to other FDA firm registration systems. Therefore, FDA estimates that re-registration will take 0.25 hours for each registrant. Because there will be entry and exit from this set of firms, there will also be new registrations once the system is fully operational. FDA estimates that initial registration under the fully operational system will take one hour.

The pool of potential registrants will be restaurants and SRFE with outlets in jurisdictions that have their own menu labeling regulations and that are not explicitly regulated under section 4205. Of the existing state and local regulations, the minimum number of outlets for which any of them currently apply is 15, and section 4205 applies explicitly to firms with 20 or more outlets. Therefore, only firms with between 15-19 outlets, inclusive, have any explicit incentive to register. However, chains with fewer outlets may chose to register, either because they are growing quickly, or because they are concerned about possible regulation, therefore, for the purposes of this analysis we include chains with between 10 and 19 outlets, inclusive. The primary source of potential registrants will be restaurant and specialty food chains, but there are significant numbers of convenience stores and grocery stores that prepare food on site and have a partial function as a take-away, or quick-service, restaurant. In addition, small chains of similar retail food establishments that operate in retail, hotel, corporate, educational, military or entertainment settings may want to register.

Because the statute preempts state and local regulations on vending machine labeling, no vending machine operators will have an incentive to register. Therefore, FDA estimates that zero vending machine operators will register with the FDA under section 4205 of the act.

According to The NPD Group's Spring 2010 ReCount report, there were 579,416 sole purpose eating and drinking establishments in the United States in the winter of 2010 (Ref. 2). Of these, 40 percent will be explicitly subject to FDA rulemaking for the Affordable Care Act because they are part of chains with twenty or more outlets (Ref. 2). Of the remaining 350,000 outlets, only those that would be subject to local or state rules concerning menu labeling would have any incentive to register. Approximately 7.5 percent of restaurant outlets are in states or localities with currently operational menu labeling regulation, principally New York City, Oregon, Philadelphia and some New York State counties (Ref. 3). NPD's Spring 2010 ReCount report shows a total of 20,000 outlets are part of chains with between 10 and 19 establishments. If outlets are evenly distributed geographically, then 1,500 outlets and 103 restaurant firms may have an incentive to register with the FDA. The hourly burden for restaurant chains is 206 hours (=100 chains x 1 responses/chain/year x 2 hours/response).

From the U.S. Census County Business Patterns data, FDA estimates that there are approximately 62,000 grocery stores in 2010. Of these, approximately 6,500 are "independents" which means that they are part of chains with fewer than 11 outlets (Ref. 4), and 35,000 are known to belong to chains with more than 20 outlets (Ref. 5). We round the remaining 20,523 outlets up to 21,000 to account for those outlets in chains with 10 or 11 establishments. County Business Patterns show that 11.5 percent of all grocery stores are in jurisdictions that have relevant menu labeling regulations. Taking 11.5 percent of 21,000 yields approximately 2,400 stores run by 167 firms. The hourly burden for grocery chains is 334 hours (=167 chains x 1 responses/chain/year x 2 hours/response).

According to Stagnito Media, there are 144,000 convenience store outlets in the US (Ref. 6). Of these, 64,000 are defined as very small "mom and pop" locations. Approximately 60,000 outlets are controlled by one of top 100 chains, each having at least 65 outlets (Ref. 7). Of the remaining 20,000, FDA estimates that half fall in the 10 to 19 outlet range. From County Business Patterns (Ref. 3), 1.6 percent of all convenience store outlets are in a jurisdiction with a local or state menu labeling regulation that does not explicitly exempt convenience stores. FDA estimates that approximately 160 convenience store outlets from 11 firms may have an incentive to register under this notice. The hourly burden for convenience store chains is 22 hours (=11 chains x 1 responses/chain/year x 2 hours/response).

Additional covered establishments, such as those operating in lodging, corporate, entertainment, and educational settings are often provided by very large firms with many hundreds or thousands of outlets, and will thus be explicitly covered by Section 4205 of the act rather than by the registration provisions. FDA estimates that an additional 81 firms, controlling approximately 1,200 outlets may have an incentive to register. The hourly burden for these additional chains is 162 hours (=81 chains x 1 responses/chain/year x 2 hours/response).

If all of these restaurant and similar retail food establishment chains choose to register with the FDA, then FDA estimates the number of firms registering in the first year would be

approximately 362 firms. At two hours per registration, the total initial hourly burden will then be 724 hours (=362 firms x 2 hours/firm).

FDA estimates that the rate of growth for chains entering the 10-19 outlet segment will match the rate of growth out of this segment, so that the number of registrants will remain constant. County Business Patterns data shows an average growth rate in the number of establishments to be two percent per year over the eight years from 1999 to 2007 for restaurants (Ref. 3). If the restaurant growth rate for outlets of approximately 2 percent per year applies to these chains, then new registrants will amount to approximately 7 per year, with the remaining 355 registrants only renewing their registration. The yearly burden for registration is estimated to be 1 hour per new registrant. Thus, the total hour burden will be 7 hours (7 firms x 1 hour/firm). The yearly burden for renewing registration is estimated to be 0.25 hour per continuing registrant. Thus, the total hour burden will be 89 hours (355 firms x 0.25 hour/firm = 88.75, rounded to 89). This yields a recurring hourly burden of 96 hours per year7 hours + 89 hours).

12b. Annualized Cost Burden Estimate

FDA estimates an initial cost burden of $24,064 with a recurring cost burden of $991. The analogous initial cost burden displayed in the fifth row of Table 2, $8,021, is a result of dividing by three the burdens that occur only in the first year, to avoid double counting in the ROCIS system. Hourly burdens are taken from the last column of Table 1. 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 this burden. We give an average the wage from restaurants and other (NAICS 722) and from grocery and convenience stores (NAICS 445) for the recurring hourly costs, weighted by the number of firms in each category (Ref. 9).

Table 2. – Estimated Costs of Hourly Burden[1]

Type of Respondent	Total Hours	Hourly Wage Rate	Total Respondent Costs
Restaurant initial	206	$10.13	$2,087
Grocery initial	334	$12.06	$4,028
C-store initial	22	$12.06	$265
Other SRFE initial	162	$10.13	$1,641
Total initial hourly costs			$8,021
New registrations	7	$10.32	$72
Re-registrations	89	$10.32	$918
Total recurring hourly costs			$991

[1] Actual first year burden hours have been divided by 3 to avoid double counting in the ROCIS system.

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

There are no capital, start-up, operating or maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

    FDA estimates the initial cost of setting up the registration system to be approximately $200,000, with recurring maintenance cost of $60,000 per year.

15. Explanation for Program Changes or Adjustments

    At the time of the emergency approval, we estimated that the total burden would be 1,755 hours. For this first extension, we now estimate that the total burden hours will be 820 hours, a reduction of 935 hours. The reduction in the estimate is due to an overestimate at the emergency approval stage. Thus, this reduction in the burden estimate is 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.

References

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