ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
UCEDD: Interview with Peer Researchers and Colleagues	100	1	0.75	75
UCEDD: Interview with Recipients of Community Services or Members of Organizations/Agencies that are Trained to Provide Community Services	100	1	0.75	75
UCEDD: Self-administered Form	20	1	8	160
P&A: Executive Director Interview	20	1	4	80
P&A: Staff Interview	60	1	0.75	45
P&A: Board of Directors (Commissioners)-Chair and Members	60	1	0.75	45
P&A: Group Interview with Policymakers and Collaborators	160	1	2	320
P&A: Interview with Recipient of Community Education	100	1	0.75	75
P&A: Interview with Clients	100	1	0.75	75
P&A: Self-administered Form	20	1	8	160
UCEDD: Interview with Director	20	1	4	80
DD Council: Group Interview with Recipients of Self-Advocacy and Leadership Education and Training	100	1	0.75	75
DD Council: Group Interview with Recipients of Education and Training to Improve Community Capacity	100	1	0.75	75
DD Council: Self-administered Form	20	1	8	160
Estimated Total Annual Burden Hours:				4,135

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–7285, *E-mail: OIRA_SUBMISSION @OMB.EOP.GOV., Attn:* Desk Officer for the Administration for Children and Families.

Dated: November 1, 2010.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2010–27855 Filed 11–3–10; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0564]

Agency Information Collection Activities; Proposed Collection; Comment Request; Restaurant Menu 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 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 information collection provisions of FDA's program of voluntary registration under the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act).

DATES: Submit either electronic or written comments on the collection of information by January 3, 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:

I. Background

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 Labeling: Registration for Small Chains Under Section 4205 of the Patient Protection and Affordable Care Act of 2010—(OMB Control Number 0910–0664)—Extension

On March 23, 2010, the President signed into law the Affordable Care Act (Pub. L. 111–148). Section 4205 of the legislation, which principally amends sections 403 (21 U.S.C. 343) and 403A (21 U.S.C. 343–1) of the Federal Food, Drug, and Cosmetic Act (the FD&C 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. The information collection requirements of FDA's program of voluntary registration under section 4205 of the Affordable Care Act were approved under the emergency processing provisions of the PRA and assigned 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 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 e-mail 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, 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 following:

- 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 of the Affordable Care Act.

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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	Number 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
C-store initial	11	1	11	2	22
Other SRFE initial	81	1	81	2	162

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Type of respondent	Number of respondents	Annual frequency per response	Total annual responses	Hours per response (average)	Total hours
Total initial hours					724
New registrations	7	1	7	1	7
Re-registrations	355	1	355	0.25	89
Total recurring hours					96

[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, semiannual reporting of firm contact and location information to FDA. FDA bases its per respondent burden on the PRA analysis for section 415 of the FD&C Act (21 U.S.C. 350d) as laid out for the proposed rule entitled "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (68 FR 5378, February 3, 2003) (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 2 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 1 hour.

The pool of potential registrants will be restaurants and SRFEs with outlets in jurisdictions that have their own menu labeling regulations and that are not explicitly regulated under section 4205 of the Affordable Care Act. 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 and 19 outlets, inclusive, have any explicit incentive to register. However, chains with fewer outlets may choose 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 onsite 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 FDA under section 4205 of the Affordable Care 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 20 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 FDA. The hourly burden for restaurant chains is 206 hours (= 100 chains × 1 responses/chain/year × 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 × 1 responses/chain/year × 2 hours/response).

According to Stagnito Media, there are 144,000 convenience store outlets in the United States (Ref. 6). Of these, 64,000 are defined as very small "mom and pop" locations. Approximately 60,000 outlets are controlled by 1 of the 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 × 1 responses/chain/year × 2 hours/response).

Additional covered establishments, such as those in 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 Affordable Care 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 × 1 responses/chain/year × 2 hours/response).

If all of these restaurant and similar retail food establishment chains choose to register with 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 × 2 hours/firm).

FDA estimates that the rate of growth for chains entering the 10 to 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 2 percent per year over the 8 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 × 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 × 0.25 hour/firm = 88.75, rounded to 89). This yields a recurring hourly burden of 96 hours per year (7 hours + 89 hours).

II. References

The following references have been placed on display in the Division of Dockets Management (*see* **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register.**)

1. Food and Drug Administration, "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," 68 FR 5378, February 3, 2003.

2. The NPD Group, "Chains System Size Trend Report for U.S. FDA," *ReCount,* Spring 2010.

3. U.S. Census Bureau, 2007, County Business Patterns, *http://www.census.gov/econ/cbp/index.html,* 2007, version date September 22, 2009.

4. Moran, M., J. McTaggart, and D. Chanil, "Looking Up, Cautiously," *Progressive Grocer* 89(3): 20–52, 2010.

5. Food Marketing Institute, Top U.S. Supermarket & Grocery Chains (by 2007 grocery sales), *http://www.fmi.org,* 2008.

6. Stagnito Media, "Directory of Convenience Stores: FAQ," *http://www.conveniencestores.com/faq.html,* accessed June 1, 2010.

7. Longo, D. "Convenience Store News: Hot Top 100," *Convenience Store News,* 45(10), pp. 27–32, August 10, 2009.

Dated: October 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–27854 Filed 11–3–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0543]

Agency Information Collection Activities; Proposed Collection; Comment Request; Importer's Entry Notice

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 revision 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 revision of an approved Office of Management and Budget (OMB) collection of information for FDA's Importer's Entry Notice. This revision reflects additional burden recognized as a result of including tobacco products to the list of FDA-regulated products under the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act).

DATES: Submit either electronic or written comments on the collection of information by January 3, 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: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.Capezutto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from 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 revision 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.

Information Request Regarding Importer's Entry Notice—(OMB Control Number 0910–0046)—Revision

On June 22, 2009, the President signed the Tobacco Control Act (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to