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

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 includes the following:

- The name, address, phone number, email 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 email 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.

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, which contained multiple comments in response to the notice.

(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 Affordable Care Act. Thus, FDA has not changed the burden estimates in table 1 of this document.

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
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, 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 "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 SRFE 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 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 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 2 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. 2003. "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: January 25, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–1994 Filed 1–28–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2001–D–0254; formerly Docket No. 2001D–0037]

Draft Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion" dated January 2011. The draft guidance document provides blood establishments with recommendations for pre-storage leukocyte reduction of Whole Blood and blood components intended for transfusion, including recommendations for validation and quality control monitoring of the leukocyte reduction process. This second draft guidance document incorporates revisions after reviewing comments on the January 2001 draft. This draft guidance replaces the draft guidance of the same title dated January 2001. This draft guidance, when