

**Final Rule on Food Labeling; Calorie Labeling of  
Articles of Food in Vending Machines**

**OMB Control No. 0910-NEW**

**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 ACA amended sections 403(q) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as well as 403A, which governs Federal preemption of State and local food labeling requirements.

Section 4205 of the ACA added section 403(q)(5)(H)(viii) of the FD&C Act to require that if an article of food is sold from a vending machine that (1) "does not permit a prospective purchaser to examine the Nutrition Facts Panel before purchasing the article or does not otherwise provide visible nutrition information at the point of purchase;" and (2) "is operated by a person who is engaged in the business of owning or operating 20 or more vending machines," then the vending machine operator must "provide a sign in close proximity to each article of food or the selection button that includes a clear and conspicuous statement disclosing the number of calories contained in the article."

Under section 403(q)(5)(H)(ix) of the FD&C Act, vending machine operators who are not subject to the new requirements of section 403(q)(5)(H)(viii) of the FD&C Act can register voluntarily with FDA to become subject to the Federal requirements. In the Federal Register of July 23, 2010 (75 FR 43182), we published a notice specifying the terms and conditions for implementation of voluntary registration, pending issuance of regulations. Subsequently we published a proposed rule on April 6, 2011 (76 FR 19237[8]) and a final rule on December 1, 2014 (79 FR 71259), to become effective December 1, 2016. FDA is requesting OMB approval of the information collection provisions in its final rule.

2. Purpose and Use of the Information Collection

To help make calorie information for vending machine foods available to prospective purchasers in a direct, accessible, and consistent manner to enable them to make informed and healthful dietary choices, section 4205 of the ACA and the rule require that vending machine operators who own or operate 20 or more vending machines, or who voluntarily elect to be covered, must provide calorie declarations for those vending machine foods for which the Nutrition Facts label cannot be examined prior to purchase or for which visible nutrition information is not otherwise provided at the point of purchase. The agency is implementing these regulations so that consumers might benefit from access to this dietary information.

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](mailto: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 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 are vending machine operators that voluntarily elect to be subject to the Federal requirements of this rule by registering with FDA.

### 3. Use of Improved Information Technology and Burden Reduction

FDA has implemented 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 use electronic means for reporting under this interim process. FDA will also 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 it wishes 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. To the extent that a small business may be impacted, the registration process is specifically designed to minimize its regulatory burden by giving it a choice as to which rules it wishes 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 its 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 the Federal Register of April 6, 2011, (76 FR 19237[8]) FDA published a proposed rule that included a section entitled "Paperwork Reduction Act" in the preamble (76 FR 19238 at 19249–19251). We received a number of comments that are discussed in the final rule (79 FR 71259, at 71284) and have included that discussion here:

(Comment) One comment stated that we did not calculate the burdens to the suppliers of vending machine food. The comment stated that these suppliers will bear the larger burden from the requirements of the final rule.

(Response) Neither section 403(q)(5)(H)(viii) of the FD&C Act nor the final rule applies to suppliers of vending machine food; instead, section 403(q)(5)(H)(viii) of the FD&C Act and the final rule establish requirements for certain vending machine operators. We recognize that a supplier of covered vending machine food may provide calorie information on front-of-package labeling and such calorie information may constitute visible nutrition information in accordance with section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act provided that the applicable requirements of § 101.8(b) are satisfied. However, neither section 403(q)(5)(H)(viii) of the FD&C Act nor the final rule requires suppliers to provide such information. As such, the final

rule does not impose burdens on suppliers of vending machine food.

(Comment) One comment stated that posting calories would not be burdensome, as most foods sold in vending machines already provide calorie information on their Nutrition Facts labels, and for foods that do not already have calorie information, labeling to disclose calories can be accomplished easily by using stickers. Another comment stated that, in light of the major beverage companies' prior commitment to putting calorie information on selection buttons, we should reduce our burden estimate.

(Response) To the extent that foods sold from covered vending machines permit a prospective purchaser to examine the Nutrition Facts label before purchasing the food or otherwise provide visible nutrition information at the point of purchase in accordance with section 403(q)(5)(H)(viii) of the FD&C Act and § 101.8(b), the vending machine operator would not be required to provide calorie declarations for such foods. In addition, we recognize that the "Clear on Calories" commitment by the American Beverage Association, which includes a pledge that calories will be displayed on selection buttons of "company-controlled vending machines," may be consistent with the calorie declaration requirements of section 403(q)(5)(H)(viii) of the FD&C Act. Our estimates of the burdens already account for the fact that many vending machine foods will not require additional nutrition analysis under this final rule. For example, we estimate in the RIA that only 723 to 963 covered vending machine operators will need to acquire nutrition information for at least some of their vending machine food.

Our estimate of the burdens and cost of nutrition analysis also takes into consideration that vending machine operators can comply with the requirements of the final rule by providing calorie declarations through less burdensome and less expensive means (e.g., a poster affixed to the front of the machine could cost, on average, \$20 per machine per year) (Ref. 1). The final rule does not prescribe the types of materials through which calories must be declared, and a sticker, for example, could be an appropriate medium to convey a required calorie declaration.

(Comment) One comment stated that our estimate on how frequently labeling would need to change is too low. The comment stated that in almost all cases, machines are restocked and serviced every 5 weeks, with busier locations stocked once or more per week. The comment stated that the restocking will require labeling changes because restocking may result in the substitution of certain products for other products or the addition of new products. The comment stated that relabeling would need to occur between 10 and 17 times per year for each machine, with some machines requiring partial relabeling at least 50 times per year.

(Response) In the preliminary RIA, we estimated an average recurring burden of between 5 and 15 minutes per vending machine per year to install or refresh the calorie displays. We said that signs would not always need to be updated every time a machine's product mix (i.e., the assortment of vending machine foods offered for sale in a vending machine at a particular time) changed. We recognize that the product mix in a particular vending machine may change with each restocking. For each machine, the rule requires operators to declare the calorie information for those articles of food that are sold from that particular vending machine. However, we would not object to a vending machine operator providing calorie declarations for articles of food that are typically offered for sale in a vending machine but may not be offered for sale at all times (for example, in cases where the article sells out, or is temporarily replaced

by another item), provided that the calorie declarations are clear and conspicuous and placed prominently. Thus, signs would not always need to be updated every time a machine's product mix changed, so long as the sign declares the calories for each article of food sold from the covered vending machine. For example, if a particular article of food is sold out, the vending machine operator would not need to design and print a new sign to remove the calorie declaration for such food. In addition, to the extent that foods sold from covered vending machines permit a prospective purchaser to examine the Nutrition Facts label before purchasing the food or otherwise provide visible nutrition information at the point of purchase in accordance with section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act and § 101.8(b), the vending machine operator would not be required to provide calorie declarations for such foods. Therefore, restocking of covered vending machines that sell such foods would not require the vending machine operator to update signs. Furthermore, in order to accommodate the occasional trial or experimental product, the sign template could, for example, be designed with blank space, on which the operator could handwrite the experimental product's name and caloric value, or place a declarative sticker next to the new product within the machine (should it have a glass/plexiglass front). The comment provided an estimate of the number of times a vending machine's sign would likely need to be replaced, or 10 to 17 times. We estimate that in accordance to the factors described in the earlier paragraphs of this response, calorie declaration signs would only need to be replaced between 1 and 4 times per year (or even zero for some products). This estimate also takes into consideration that vending machine operators have the flexibility to choose a medium (e.g., stickers, posters) and a format (e.g., individual signs per covered vending machine food; sign(s) in, on, or adjacent to the vending machine) for the calorie declaration that will make the most sense for a particular vending machine operator depending on the variability of products that the operator carries and the frequency of restocking.

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

*Reporting Burden*

Table 1.--Estimated Annual Reporting Burden: Voluntary Registration<sup>1</sup>

21 CFR Part 101	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Initial Burden (annualized over 3 years)					
§ 101.8(d) Initial Registration	13	1	13	2	26
Annual Burden					
§ 101.8(d) Registration Renewal	19	1	19	0.5 (30 minutes)	9.5
Total Burden Hours					35.5

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

At this time, FDA lacks data on the number of vending machine operators with fewer than 20 machines that might voluntarily register to comply with this final rule. We do not expect the net benefit for voluntary registration by any non-covered vending machine operators to be positive and in the RIA of the final rule (references may be found in the agency’s docket (FDA-2011-F-0171)) we indicate that as of the conducting our analysis, no vending machine operators had voluntarily registered with FDA. Therefore we did not estimate a significant burden. However, in the event that a few will register anyway, or find some positive incentive to do so, for the purposes of this PRA analysis, we estimate the burden such operators will face. We estimate there are approximately 757 vending machine operators with fewer than 20 machines; this number is based on the mean estimate of the low and high counts of firms with less than \$50,000 in annual revenue from the RIA. We estimate that 5 percent of vending machine operators with fewer than 20 machines may voluntarily register to become subject to the final requirements, or 38 operators. We estimate a burden of approximately 2 hours per initial registration, which yields a total burden of 76 hours (38 total operators × 2 hours per response). Annualizing this number over 3 years yields a rounded 13 respondents per year (5 percent × 757 operators / 3 years). With an annualized estimate of 13 vending machine operators and one registration per vending machine operator at 2 hours per registration, we estimate the initial hourly burden for these operators is 26 hours.

We expect that renewal registrations after the first year will require substantially less time because operators are expected to be able to affirm or update the existing information in an online account in a way similar to other FDA firm registration systems. Therefore, we estimate that re-registration will take 0.5 hours for each registrant. This would indicate that biennial registration would impose a burden of 19 hours (38 operators × 0.5 hours) every 2 years, or 9.5 hours every year (18 operators every year × 0.5 hours).

### *Recordkeeping Burden*

The preamble to the proposed rule (76 FR 19238 at 19249-19251) provided an estimate of the recordkeeping burden, which consisted of the burden associated with calorie analysis and the burden associated with generating, providing, or maintaining records. Upon further consideration, we have omitted the burden estimate associated with generating, providing, or maintaining records previously provided in table 3 of the proposed rule because the rule does not require vending machine operators to generate, provide, or maintain records. Further, as discussed in the final rule, we have included a burden estimate for calorie analysis as part of the third party disclosure burden, since the “total time, effort, or financial resources expended by [covered vending machine operators]” (5 CFR 1320.3(b)) to declare calories for covered vending machine food likely includes time, effort, or financial resources to determine the calorie content of such food.

### *Third-Party Disclosure Burden*

Table 2.--Third Party Disclosure Burden

21 CFR Part 101	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure (in hours)	Total Hours	Capital Costs
§ 101.8(c)(2)(i) Calorie Analysis	282	11	3,102	1	3,102	
§ 101.8(c)(2)(ii) Template Design	3,279	5	16,395	2	32,790	
§ 101.8(c)(2)(ii) Sign Creation	3,279	125	409,875	0.475 (28.5 min.)	194,710	\$4,671,047
§ 101.8(e)(1) Contact Information	3,279	125	409,875	0.025 (1.5 min.)	10,248	
§ 101.8(c)(2)(ii) Sign Installation	1,868,419	1	1,868,419	0.083 (5 min.)	155,079	
§ 101.8(c)(2)(ii) Sign Information Update	511,576	2	1,023,152	0.5 (30 min.)	511,576	
§ 101.8(c)(2)(ii) Sign Replacement	1,755,986	2	3,511,972	0.17 (10 min.)	597,035	
§ 101.8(c)(2)(ii) Bulk Machine Signage	128,533	1	128,533	0.025 (1.5 min.)	3,213	
<b>Total Burden</b>					<b>1,507,753</b>	<b>\$4,671,047</b>

### *Third-Party Disclosure Requirements: Calorie Analysis*

A calorie analysis entails the burden of determining calorie content for covered vending machine food. Most foods sold from vending machines provide the nutrition labeling required by section 403(q) of the FD&C Act and §101.9, including calorie content information, which means that calorie content for many covered vending machine foods is already available on the Nutrition Facts labels for such foods. In that case, vending machine operators will not need to determine the calorie content of such foods because they can simply declare the calorie

information they find on the Nutrition Facts label. Nevertheless, some operators may need to determine calorie information for those vending machine foods that may not bear Nutrition Facts labels or otherwise provide visible nutrition information at the point of purchase in accordance with section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act and §101.8(b). An operator may obtain the necessary calorie information from nutrient databases, cookbooks, or laboratory analyses. Calorie analysis will most likely only be needed for vended food items such as refrigerated, frozen, can/bowl, or other shelf-stable main meal items, hot cup beverages, and cold cup beverages. We anticipate that vending machine operators are likely to generate and maintain a record of the information on which they relied to determine the total calories posted for the vending machine food.

As stated in the RIA, we estimate the mean number of vending machine operators that need calorie analysis to be 847. Annualizing this estimate over 3 years yields 282 operators. We also estimate the range of products available in a typical machine for each of the three most commonly sold product categories that are likely to require a calorie analysis, or 3 percent of food items, 5 percent of hot beverages, and 1 percent of cold cup beverages. We estimate that food machines typically offer between 10 and 25 different items, and both hot beverage and cold cup beverage machines typically offer between 5 and 10 items. From this, we estimate each vending machine operator will require a calorie analysis for 11 items, on average. These estimates were based upon conversations with vending machine operators and our survey of various vending machine models that vend these types of food and beverage. Based on data from FDA's Recordkeeping Cost Model, we estimate the time needed to determine the calorie content of each covered vending machine food to be approximately 1 hour. Our estimate for the burden hours that would be required for new calorie analysis is then 9,317 hours (847 operators × 11 products needing analysis × 1 hour per analysis). Annualizing this value over 3 years yields 3,102 hours (847 operators / 3 years × 11 products needing analysis × 4 hours per analysis). (847 operators/ 3 years = 282 operators per year.) There will not be capital costs associated with a calorie analysis.

#### *Third-Party Disclosure Requirements: Calorie Declaration Signs*

Under this rule, covered vending machine operators with 20 or more vending machines and vending machine operators that voluntarily register to become subject to the Federal requirements, must disclose calorie information by providing calorie declaration signs in, on, or adjacent to their vending machines to a third party who will most often be the prospective purchaser or consumer. Our burden estimate for the calorie declaration signs is based on the total time it takes for vending machine operators to produce and install the calorie declaration signs. We separately estimate the burden for two kinds of vending machines, non-bulk and bulk machines. For non-bulk vending machines, we estimate the burden to operators as the initial time it takes them to develop the calorie disclosure signage, which includes the time for the sign template design (i.e. the creation of generalized sign templates), sign creation (i.e. using templates to design machine-specific signs), and installation; and then the time for the recurring burden, which includes the time to update or change calorie information and the physical replacement of the disclosure signage when the product mix of the machine changes. For bulk machines, we estimate the burden to operators for the cost of individual calorie labels. (We assume that individual calorie declaration stickers will be placed on the face of each individual bulk vending machine, since each machine only vends a single product.) Recurring updates to signage will only likely be required for non-bulk, non-beverage machines since the

product mixes of these machines are changed regularly, while the product mix for bulk machines is unlikely to change.

We estimate there is an average of 9,838 (9,800 covered non-bulk + 38 voluntary) vending machine operators subject to the rule. ( $9,838/3 = 3,279$  annualized). Our estimate for the average number of non-bulk vending machines that will require declaration signage is based upon data obtained from the Vending Times Survey and National Automatic Merchandising Association (NAMA) and the Economic Census, and as summarized in table 8 of the final RIA. We estimate there is an average of 5.61 million non-bulk vending machines. Digital signage is an emerging technology, and according to NAMA approximately 0.1 percent of all vending machines in operation currently have electronic video displays capable of providing calorie information, or approximately 4,014 to 5,670 vending machines. Subtracting the number of vending machines with the electronic video from the total machine count yields an average of 5.611 million vending machines that will need signage. We expect the number of vending machines that will require signage to decline over time as manufacturers continue to add the required calorie information to the principal display panel of the package as part of “front of package labeling,” and because we anticipate greater use of electronic video displays on vending machines. In addition, to the extent that covered vending machines sell foods that permit prospective purchasers to examine the Nutrition Facts label before purchase or otherwise provide visible nutrition information at the point of purchase in accordance with section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act and § 101.8(b), this analysis may overestimate the burden estimate for calorie declaration signs.

We estimate the time it takes for the one-time design of a calorie disclosure sign template to be 2 hours. The number of templates a given firm would need to design to produce signs that comply with the rule may vary based upon the number of different types of products the firm purveys. We estimate a range of one to ten templates would be necessary. We base this range on the eight general food and beverage vending categories monitored by the Vending Times Census, plus two additional templates to account for the existence of combination machines, which vend more than one general product type (e.g. snacks and cold canned beverages)--see table 4 of the final RIA (Refs. 1, 6 of the final rule). Since not all firms will sell items from each of the general food categories, we estimate that on average, firms will sell items from approximately four general food categories and operate one set of combination machines, requiring the need to develop (on average) five templates. At 2 hours per template, the total initial burden for designing templates comes to an estimated 98,380 hours ( $9,838$  operators  $\times$  5 templates  $\times$  2 hours per template). Annualizing this value over 3 years yields a burden of 32,790 hours ( $9,838$  operators / 3 years  $\times$  5 templates  $\times$  2 hours per template). There are no capital costs associated with template design.

We estimate the time it takes to enter calorie information into a single sign template and prepare it for printing to be 0.475 hours. Again, we estimate the number of machine configurations to be 125. The count of machine configurations is a general estimate of the number of different types of machines an operator uses to sell its products, and takes into account that fact that a machine’s specific product mix will depend on locational characteristics (e.g. office vs. hotel) and the type of machine (e.g. beverage vs. snack). We estimate the total initial burden for sign creation using the predesigned templates to be 584,131 hours ( $9,838$  operators  $\times$  125 sign formats  $\times$  0.475 hours per sign). Annualized over 3 years, this burden becomes 194,710 hours ( $9,838$  operators / 3 years  $\times$  125 signs  $\times$  0.475 hours per sign). Capital

costs associated with sign creation correspond to the cost of paper and ink for printing the signs. As estimated in the RIA (Ref. 1 of the final rule), the capital costs are \$2.50 per sign, which results in a total capital cost of \$14,013,143 [(5,604,914 covered non-bulk machines + 343 voluntarily registered machines) × \$2.50 per machine]. Annualized over 3 years, this value becomes \$4,671,048 (5,605,257 machines / 3 years × \$2.50 per machine).

Vending machine operators must also provide their contact information on each vending machine selling covered vending machine food as required under §101.8(e)(1). We assume that vendors that do not already have a sign or label with their contact information will add their contact information into the initial sign design. We estimate the time it takes to include contact information is 1.5 minutes (0.025 hours) for each sign. We estimate the total initial burden for including contact information on the predesigned templates to be 30,744 hours (9,838 operators × 125 sign formats × 0.025 hours per sign). Annualized over 3 years, this burden becomes 10,248 hours (9,838 operators / 3 years × 125 signs × 0.025 hours per sign). There are no capital costs associated with adding contact information. (Some States have licensing requirements for vending machine operators, and some of these licensing requirements already require the vending machine operator's license or contact information to be displayed on the vending machine. If the contact information displayed on a vending machine due to State or local requirements includes some but not all of the contact information required under §101.8(e)(1), the vending machine operator is required to display the remaining contact information required under §101.8(e)(1) in a manner specified under §101.8(e)(1). We do not have an estimate of the number of machines already in compliance; to the extent that some operators are already in compliance, we overestimate the burden of third-party disclosure.)

We estimate the time it takes to install a sign onto a single machine to be 5 minutes (0.083 hours) for each sign. With 5,605,257 machines (5,604,914 covered machines + 343 voluntarily registered machines), we estimate the annual burden for initial sign installation to be 465,236 hours (5,605,257 machines × 1 sign per machine × 0.083 hours installation). Annualized over 3 years, this burden becomes 155,079 hours (5,605,257 machines / 3 years × 1 sign per machine × 0.083 hours installation). (5,605,257 machines / 3 years = 1,868,419 machines per year.) There are no capital costs associated with sign installation.

We divide the estimates for the recurring burden of non-bulk third-party disclosure into two parts: updating calorie sign information for changes in the product mix (which involves updating the digital format); and physical sign replacement (which involves printing and installation). We estimate the average number of product configurations for machines that will experience regular changes to their product mix to be 52. This value is lower than the overall average of 125 since some machines (such as beverage machines) do not experience regular changes to the product mix. We estimate the average number of times that calorie signs will need to be updated to be twice per year. Finally, we estimate the time it takes to update a single sign using the predesigned template to be 0.5 hours. Thus, the total burden for updating sign information is 511,576 hours [511,576 records (made up of 9,838 operators × 52 product configurations) × 2 updates per year × 0.5 hours per update].

We estimate the annual number of covered machines that will need regular sign replacement to be 1,755,986 machines (1,755,879 covered machines + 107 voluntarily registered machines). We estimate the time it takes to remove and replace old signs with new signs to be 0.17 hours

(10 minutes). Thus, the total annual burden for replacing signs is 597,035 hours (1,755,986 machines × 2 replacements per year × 0.17 hours per replacement). There are no capital costs associated with updating sign information or physical sign replacement.

We estimate there is an average of 385,600 covered bulk vending machines, based on data obtained from the Vending Times Census and NAMA (Refs. 6, 8 of the final rule). We assume each bulk machine vends a single bulk product, and we further assume they will choose the most economical signage, which means they are likely to use a small sticker on the face of each machine. We estimate the time to print and apply each sticker is 1.5 minutes (0.025 hours). Thus, the total burden for bulk machine signage is 9,640 hours (385,600 bulk machines × 0.025 hours per machine). Annualized over 3 years, this value becomes 3,213 hours (385,600 /3 years × 0.025 hours per machine). (385,600 /3 years = 128,533 machines per year.)

*12b. Annualized Cost Burden Estimate*

FDA estimates an initial cost burden of \$208 with a recurring cost burden of \$228. The analogous initial cost burden displayed in the third row of Table 2, \$436, 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 of a non-supervisory employee of a vending machine operation as \$16 per hour. Including a 50 percent increase for overhead costs and employee benefits, the average hourly cost of an employee in this sector is approximately \$24 per hour. (Ref. 9 of the final rule).

*Table 2. – Estimated Costs of Hourly Burden<sup>1</sup>*

21 CFR Part 101	Total Hours	Hourly Wage Rate	Total Respondent Costs
Initial Burden (annualized over 3 years)			
§ 101.8(d) Initial Registration	26	\$8.00	\$208
Annual Burden			
§ 101.8(d) Registration Renewal	9.5	\$24.00	\$228
Total Burden Hours	35.5		\$436

<sup>1</sup> Actual first year burden costs 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

Estimated capital, start-up, operating or maintenance costs associated with this collection of information total \$4,671,047 as identified in Row 3 of Table 2 (Third Party Disclosure Burden) above. These costs are associated with sign creation, where we approximate a cost of \$2.50 per sign, totalling \$14,013,143 [(5,604,914 covered non-bulk machines + 343 voluntarily registered machines) × \$2.50 per machine]. Annualized over 3 years, this equals \$4,671,048 (5,605,257 machines/3 years × \$2.50 per machine).

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

Because of substantial revisions since issuance of the underlying proposed rule (76 FR 19237[8]) for this collection, FDA discontinued its approval authority for the original provisions found under OMB Control No. 0910-0664 upon its expiration in 2014. We are now, therefore, submitting the request as a new information collection.

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.