

United States Food and Drug Administration

Food Labeling;
Calorie Labeling of Articles of Food in Vending Machines
and Nutrition Labeling of Standard Menu Items in Restaurants
and Similar Retail Food Establishments

OMB Control No. 0910-0782

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA or we) regulations under 21 CFR 101 and the associated collection instrument Form FDA 3757. The Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires the disclosure of certain calorie labeling of articles of food in vending machines, as well as nutrition information for standard menu items in certain restaurants and retail food establishments.

Specifically, section 403(q)(5)(H)(viii) of the FD&C Act requires 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.*”

Section 403(q)(5)(H)(ix) also provides for the voluntary registration of vending machine operators who are not otherwise subject to the requirements of section 403(q)(5)(H)(viii). Finally, sections 201(n), 403(a)(1), 403(f), 403(q)(5)(H), and 701(a) of the FD&C Act requires restaurants and similar retail food establishments that are part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items to provide calorie and other nutrition information for standard menu items, including food on display and self-service food.

Sections 101.8 and 101.11 provides that respondents with a chain of 20 or more locations will disclose nutritional information of certain foods for consumers of food products for the purpose of making informed dietary choices. We also offer registration for respondents who wish to voluntarily participate with this information collection activity, for which we developed Form FDA 3757 entitled, “*DHHS/FDA Menu and Vending Machine Labeling Voluntary Registration*” to assist respondents in this regard. To keep the registration active, a respondent renews their registration every other year within 60 days prior to the expiration of the respondent’s current registration with FDA, or it will automatically expire.

We therefore request OMB extension of approval of the information collection provisions found in 21 CFR part 101 and the associated collection instrument Form FDA 3757.

2. Purpose and Use of the Information Collection

We use the information collection to help determine compliance with regulatory requirements. Third-party disclosure requirements are used by consumers of food products for the purpose of making informed dietary choices. To assist respondents with the reporting elements of the information collection, we developed Form FDA 3757. The information collection also serves to fulfill FDA's mandate under the FD&C Act to promote and protect the public health by ensuring the safety of food products available for human consumption.

Description of Respondents: Respondents to this collection of information include vending machine operators and restaurants and similar retail food establishments subject to the requirements of 21 CFR 101 as well as those entities that voluntarily participate with provisions of this collection of information.

3. Use of Improved Information Technology and Burden Reduction

We have established a registration process consisting of Form FDA 3757 and associated instructions. We estimate all respondents (100%) will use electronic means for reporting under this process. Additionally, we have issued the following guidance documents to assist respondents with the information collection:

- *Menu Labeling: Supplemental Guidance for Industry;*
- *Draft Guidance for Industry: Calorie Labeling of Articles of Food in Vending Machines;*
- *Guidance for Industry: Calorie Labeling of Articles of Food in Vending Machines; Small Entity Compliance Guide;*
- *Guidance for Industry: A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods - Part I;*
- *Guidance for Industry: A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods - Part II; and*
- *Guidance for Industry: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Small Entity Compliance Guide.*

These guidance documents are available on our website at www.fda.gov.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

We estimate that no small businesses (0%) will be affected by the information collection. To the extent that a small business may be impacted, the registration process is specifically designed to minimize burden by giving a choice as to voluntarily comply. The registration process is voluntary and is the minimal amount of burden that we can impose in order to give firms this choice and to give regulatory authorities the information they need to enforce applicable statutes. If a small business chooses to register, we aid small businesses in dealing with the requirements of vending machine and menu labeling requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. Additional assistance is available for small businesses via the agency's website at <https://www.fda.gov/industry/small-business-assistance>.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with regulatory requirements.

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), we published a 60-day notice requesting public comment on the proposed collection of information in the *Federal Register* of December 4, 2020 (85 FR 78334). We received four comments. Generally, the comments related to the necessity and public utility of the collections of information and ways to minimize the burden of the collection on respondents.

Comment: Some comments asserted that menu labeling is not helpful and, in fact, may increase the risk of eating disorders. Comments added that a healthy food cannot be based on calories alone.

Response: The purpose of displaying calories on menus are to assist consumers to make informed dietary choices. We agree that calories alone do not determine a healthy food, but other factors should be considered such as its nutritional content (e.g., the amount of sodium or sugar in the food).

Eating disorders are a serious problem that should be addressed by the appropriate health professionals. However, data does not indicate that the display of calorie information is the cause of eating disorders.

Comment: One comment suggested that restaurants should be provided information about the potential impacts of calorie labeling on menus and be allowed to independently decide whether to disclose calories. The comment continued that calorie labeling could place added strain on establishments and may not have the intended outcome. Another comment suggested that all restaurant chains should have calorie labeling, not just those with 20 or more locations.

Response: The FD&C Act requires the disclosure of certain calorie labeling for standard menu items in certain restaurants and retail food establishments. Section 101.11 provides that respondents with a chain of 20 or more locations will disclose nutritional information of certain foods for consumers of food products for the purpose of making informed dietary choices. We are sensitive to the burden this could place on small businesses, so the labeling requirement is limited to chains of 20 or more locations. However, we offer registration for respondents who wish to voluntarily participate with the menu labeling requirement. There may be more than one reason why a firm may want to voluntarily participate in the registration process, but one benefit would be for smaller chains in multiple locations to follow the same federal requirements rather than be subject (potentially) to differing state/local requirements for their various locations. The registration process is specifically designed to minimize burden by giving a choice to small businesses to voluntarily comply with the menu labeling requirement.

Comment: Another comment suggested that resources should be diverted to nutrition and health programs instead of calorie labeling on menus.

Response: We have a number of initiatives to promote eating a healthier diet. We would suggest visiting FDA’s Nutrition Education Resources & Materials webpage at <https://www.fda.gov/food/food-labeling-nutrition/nutrition-education-resources-materials>.

Comment: One comment agreed that vending machines should display the number of calories for a product because of questionable dietary decisions made late at night.

Response: We agree the display of the number of calories helps consumers make informed dietary choices.

9. Explanation of Any Payment or Gift to Respondents

We do 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.

Privacy Act

In preparing this supporting statement, we consulted with our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII) or other data of a personal nature. PII is collected in the context of the subject individuals’ professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form 3757, “*The Menu and Vending Machine Labeling Voluntary Registration*” is name, work email address, and work telephone numbers for the primary contact at a business.

The FD&C Act, as amended, requires the disclosure of certain calorie labeling of articles of food in vending machines, as well as nutrition information for standard menu items in certain restaurants and retail food establishments. Specifically, 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. We also provide for the voluntary registration of vending machine operators who are not otherwise subject to the new requirements of section 403(q)(5)(H)(viii). Finally, the FD&C Act requires restaurants and

similar retail food establishments that are part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items to provide calorie and other nutrition information for standard menu items, including food on display and self-service food.

11. Justification for Sensitive Questions

This information collection does not involve any questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden¹

Activity Using Form FDA 3757; 21 CFR	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Initial Registration for Vending Machine Labeling; 101.8(d)	13	1	13	2	26
Registration Renewal for Vending Machine Labeling; 101.8(d)	19	1	19	0.5 (30 minutes)	9.5
Initial Registration for Menu Labeling; 101.11(d)	3,559	1	3,559	2	7,118
Registration Renewal for Menu Labeling; 101.11(d)	5,340	1	5,340	0.5 (30 minutes)	2,670
Total					9,823.5

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

Table 2.--Estimated Recordkeeping Burden¹

Activity; 21 CFR	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Record (in hours)	Total Hours
Initial Burden (Annualized over 3 years)					
Initial Nutrition Analysis; 101.8(c)(2)(i)(A)	69,017	1	69,017	0.25 (15 minutes)	17,254
Annual Burden					
Recurring Nutrition Analysis; 101.8(c)(2)(i)(A)	30,059	1	30,059	0.25 (15 minutes)	7,515
Total					24,769

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

Table 3.--Estimated Annual Third-Party Disclosure Burden¹

Activity; 21 CFR	Number of Respondents	Number of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure (in hours)	Total Hours
Calorie Analysis; 101.8(c)(2)(i)	282	11	3,102	1	3,102
Calorie Declaration Signage; 101.8(c)(2)(ii)	3,279	2,122	6,958,038	0.21 (12.5 minutes)	1,461,188
Vending Operator Contact Information; 101.8(e)(1)	3,279	125	409,875	0.025 (1.5 minutes)	10,247
Total					1,474,537

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

12b. Annualized Cost Burden

We believe any costs incurred by respondents to the information collection would be nominal. Rather, costs associated with the labeling of food products for human consumption are reflected under OMB control no. 0910-0381: *Food Labeling Regulations*.

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

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

14. Annualized Cost to the Federal Government

We estimate a \$60,000 annual cost to the Federal government for maintaining the registration system for both the vending machines and menu labeling.

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

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.