U.S. 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, we or us) regulations. The Federal Food, Drug, and Cosmetic Act (FD&C Act or the 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. Previously, we established distinct ICRs (OMB Control Nos. 0910-0782 and 0910-0783) for these collections, however, because regulations establishing all information collection elements are codified under 21 CFR Part 101, include similar collection activities, and utilize the same collection instrument, we consolidated them here.

Specifically, section 403(q)(5)(H)(viii) of the 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 new 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 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. Again, the regulations also establish the terms and conditions for voluntary registration by establishments that are not otherwise subject to the requirements.

We therefore request OMB approval of the information collection provisions under 21 CFR Part 101 as discussed below, and the associated collection instrument Form FDA 3757, "*DHHS/FDA MENU AND VENDING MACHINE LABELING VOLUNTARY REGISTRATION*."

2. Purpose and Use of the Information Collection

FDA uses 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 (referenced above). The information collection also serves to fulfill FDA's mandate under the 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 restaurants and similar retail food establishments that voluntarily elect to be subject to the Federal requirements of this rule by registering with FDA. These establishments include chain retail food establishments and eating and drinking places such as full- and limited-service restaurants, snack bars (including, for example, ice cream, donut, and bagel shops and similar establishments), cafeterias and drinking places, managed food service facilities, grocery stores, supermarkets, convenience stores, general merchandise stores, lodging facilities, recreational venues, sports venues, performing arts venues, and movie theaters.

3. Use of Improved Information Technology and Burden Reduction

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 Additionally, we have issued the following draft guidance documents to assist respondents with the information collection:

- Draft Guidance for Industry: Menu Labeling Supplemental Guidance
- 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
- Constituent Update: FDA Extends Menu Labeling Compliance Date to 2018
- 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 (Menu Labeling Requirements in Accordance with 21 CFR 101.11)
- 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. Because OMB Control No. 0910-0783 contains similar information collection requirements and accompanying activity, we have consolidated into the instant collection and have discontinued the former collection upon this submission.

5. Impact on Small Businesses or Other Small Entities

FDA estimates 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 which rules the small business wishes to follow. The registration process is voluntary, and is the minimal amount of burden that FDA 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, 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 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), FDA published a 60 day notice for public comment in the Federal Register of December 12, 2017 (82 FR 58425). A number of comments were received in response to the notice. The comments were generally supportive of the information collection, but included concerns the potential effect ongoing or delayed rulemaking to establish specific packaging requirements (e.g., font-size of labeling, compliance dates) might have on the associated third-party disclosure burden. Other comments questioned whether FDA needed all data currently being sought by the applicable regulations and suggested the registration schedule be relaxed, especially given the small number of respondents.

FDA appreciates these comments. We are also mindful of the substantive feedback provided in the comments beyond the scope of those solicited under the PRA and have included them in the appropriate agency dockets for consideration. At the same time, the public comments we received nor our own evaluation suggested we revise our original burden estimate figures and so retain those currently approved and identified in ***Question 12***, below.

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

We estimate the burden of the information collection as follows:

12 a. Annualized Hour Burden Estimate

Table 1 – Estimated Annual Reporting Burden[1]

21 CFR Part 101.8 and 101.11 Registration Using Form FDA 3757	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response (in hours)	Total Hours
101.8(d); initial registration	13	1	13	2	26
101.8(d); registration renewal	19	1	19	0.5 (30 mins.)	9.5
101.11(d) initial registration	3,559	1	3,559	2	7,118
101.11(d) registration reviewal	5,340	1	5,340	0.5 (30 mins.)	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 Burden[1]

21 CFR Part 101	Number of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Record	Total Hours
Initial Burden (Annualized over 3 years)					
§ 101.8(c)(2)(i)(A); Initial nutrition analysis	69,017	1	69,017	0.25 (15 minutes)	17,254
Annual Burden					
§ 101.8(c)(2)(i)(A); Recurring nutrition analysis	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 Burden[1]

21 CFR Part 101	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Avg. Burden per Disclosure (in hours)	Total Hours
§ 101.8(c)(2)(i); calorie analysis	282	11	3,102	1	3,102
§ 101.8(c)(2)(ii); calorie declaration signage	3,279	2,122	6,958,346	.21 (12.5 mins.)	1,461,188
§ 101.8(e)(1); vending operator contact information	3,279	125	409,875	0.025 (1.5 mins.)	10,247
TOTAL					1,474,537

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

These figures are based on our analyses in support of the underlying rulemaking establishing the information collections. We continue to evaluate the collection burden and solicit public comment, noting that the effective dates and/or compliance dates for certain provisions have not yet been realized.

12.b. 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 and/or Recordkeepers/Capital Costs

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

14. Annualized Cost to the Federal Government

FDA assumes an estimates initial cost of setting up the registration system for both the vending machine and menu labeling collections to be approximately $200,000, with recurring maintenance cost of $60,000 per year. Having realized costs for registration establishment, we retain a $60,000 annual cost estimate to the Federal government.

15. Explanation for Program Changes or Adjustments

This information collection has been revised to include burden previously accounted for under OMB Control No. 0910-0783. The information collection also reflects nominal adjustments where, upon consolidating collections, we refined our estimate to avoid duplicative burden associated with like collection activities. As shown in reginfo.gov this will reflect an overall increase to collection OMB Control No. 0910-0782 by 107,667 annual responses and 1,341 hours. At the same time, the information collection burden from OMB

Control No. 0910-0783 including 334,219 annual responses and 498,508 hours has been eliminated.

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.