

**Final Rule on Nutrition Labeling of Standard Menu Items in Restaurants
and Similar Retail Food Establishments Under Section 4205 of the
Patient Protection and Affordable Care Act of 2010**

OMB Control No. 0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

To implement the nutrition labeling provisions of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act or ACA), the Food and Drug Administration (FDA or we) is requiring disclosure of certain nutrition information for standard menu items in certain restaurants and retail food establishments. The ACA, in part, amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act), among other things, to require 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. Under provisions of the ACA, restaurants and similar retail food establishments not otherwise covered by the law may elect to become subject to these Federal requirements by registering every other year with FDA. Providing accurate, clear, and consistent nutrition information, including the calorie content of foods, in restaurants and similar retail food establishments will make such nutrition information available to consumers in a direct and accessible manner to enable consumers to make informed and healthful dietary choices. Thus, under sections 201(n), 403(a)(1), 403(f), 403(q)(5)(H), and 701(a) of the FD&C Act, we have issued a final rule to support this public health objective.

We have revised our labeling regulations by adding new §101.11 to require that covered establishments provide calorie and other nutrition information for standard menu items, including food on display and self-service food. Also, we are establishing the terms and conditions for voluntary registration by establishments that are not otherwise subject to the requirements of section 4205 of the ACA but elect to become subject to such requirements.

2. Purpose and Use of the Information Collection

The information provided to FDA will help Federal, state or local officials determine which jurisdiction's requirements apply to the firm. 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 restaurants and similar retail food establishments includes:

- 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.

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 will 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

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 allows firms to manage their registration information, and that minimizes burden by allowing firms to re-register by either changing only information elements 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 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 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 19191[2]) FDA published a proposed rule that included a section entitled, "Paperwork Reduction Act of 1995." One comment regarding our analysis of the burdens was received. We discussed the comment in the publication of our final rule in the Federal Register of December 1, 2015 (79 FR 71155[6], at 71245) and discuss it again here. The comment stated that the recordkeeping burdens of the proposed rule would impose millions of dollars in cost per year and that these burdens are needless. The agency disagrees. Providing accurate, clear, and consistent nutrition information, including the calorie content of foods, in restaurants and similar retail food establishments will make such nutrition information available to consumers in a direct and accessible manner and enable them to make informed and healthful dietary choices.

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

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

Reporting Burden

Table 1.--Estimated Reporting Burden¹

| 21 CFR Part 101 | No. of Respondents | No. of Responses per Respondent per year | Total Annual Responses | Average Burden per Response (in hours) | Total Hours |
|--|--------------------|--|------------------------|--|-------------|
| Initial Burden (annualized over 3 years) | | | | | |
| § 101.11(d) Initial Registration | 3,559 | 1 | 3,559 | 2 | 7,118 |
| Annual Burden | | | | | |
| § 101.11(d) Registration Renewal | 5,340 | 1 | 5,340 | 0.5 (30 minutes) | 2,670 |
| Total Burden Hours | | | | | 9,788 |

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

At this time, we lack data on the number of restaurants and similar retail food establishments that might voluntarily register to comply with this final rule. We do not expect the net benefit for voluntary registration for many non-covered establishments to be positive and in the RIA (Ref. 42 of the final rule) we indicate that as of the conducting of this analysis, no establishments have voluntarily registered with FDA. Therefore we did not estimate a significant burden in the RIA. However, in the event that a few register anyway, or find positive incentive to do so, for the purposes of this PRA analysis, we estimate the burden such establishments will face. We believe that implementation of the final rule, and the resulting attention to the nutrition content of standard menu items, may give non-covered establishments an incentive to voluntarily disclose calorie and other nutrition information. We believe that the only types of establishments that would likely face a positive incentive to voluntarily register are some restaurants and some grocery, convenience, and general merchandise stores that do not already provide this information in some form or another at the point of purchase. We estimate that 5 percent of these establishments may register, or 10,678 [(5% volunteer x 47% no nutrition info x 348,200 non-covered restaurants) + (5% volunteer x 49,900 non-covered grocery, convenience, and general merchandise stores)] (Refs. 44 and 45 of the final rule). We estimate it will require approximately 2 hours per initial registration. Given 10,678 establishments and one initial registration per establishment at 2 hours per registration, we estimate the initial hourly burden for these establishments is 21,356 hours (10,678 establishments x 1 initial registration per establishment x 2 hours per registration). Annualizing this value over 3 years yields

7,118 hours per year (10,678 establishments / 3 years x 1 initial registration per establishment x 2 hours per registration). (10,678 establishments / 3 years = 3,559 establishments per year.)

We expect that renewal registrations will require substantially less time because establishments 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. We estimate that re-registration will take 30 minutes (0.5 hours) for each registrant. This would indicate that biennial registration would impose a burden of 5,340 hours (10,678 establishments x 0.5 hours) every 2 years, or 2,670 hours every year (10,678 establishments / 2 years x 0.5 hours).

Recordkeeping Burden

Table 2.--Estimated Recordkeeping Burden¹

| 21 CFR Part 101 | No. 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 Records | 69,017 | 1 | 69,017 | 0.25 (15 minutes) | 17,254 |
| Annual Burden | | | | | |
| § 101.8(c)(2)(i)(A) Recurring Nutrition Analysis Records | 30,059 | 1 | 30,059 | 0.25 (15 minutes) | 7,515 |
| Total Burden Hours | | | | | 24,769 |

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

Initial Nutrition Analysis

We estimate the annual number of the largest restaurant chains that will need to produce substantiation of their standard menu items to be 541 (503 covered restaurant chains + 38 voluntary restaurant chains) with an average of 117 unique menu items that will require an initial nutrition analysis. This leads to 63,297 (541 chains x 117 items) individual chains-specific restaurant records. In addition to chain-level nutrition analysis, each individual restaurant establishment will likely have a small variety of standard menu items that are unique to the individual establishment. We estimate there are 11,684 restaurant establishments (10,866 covered + 818 voluntary) with establishment-specific items. Each of these restaurant establishments has an average of five establishment-specific menu items. This leads to 58,420 (11,684 establishments x 5 items) individual establishment-specific restaurant records.

In addition to restaurants, other similar retail food establishments have both chain-specific and establishment-specific menu items. Other covered retail food establishments include: Grocery stores, supermarkets, convenience stores, general merchandise stores, lodging facilities, recreational venues, sports venues, performing arts venues, and movie theaters. We estimate there are 691 grocery, convenience, and general merchandise (GCGM) store chains (660 covered + 31 voluntary) with an average of 40 menu items each (= 27,640 records); 5,309 GCGM establishments (5,060

covered + 249 voluntary) with an average of 5 establishment-specific menu items each (= 26,545 records); 50 managed food service (MFS) chains with an average of 80 menu items (= 4,000 records); 450 MFS establishments with an average of 5 establishment-specific menu items (= 2,250 records); 100 lodging chains with an average of 40 menu items (= 4,000 records); 620 lodging establishments with an average of 5 establishment-specific menu items (= 3,100 records); 250 sports, recreation and entertainment (SRE) chains with an average of 59 menu items (= 14,750 records); and 610 SRE establishments with an average of 5 establishment-specific menu times (= 3,050 records). In total, we estimate there are 207,052 records (63,297 restaurant chain-level + 58,420 restaurant establishment-level + 27,640 GCGM chain-level + 26,545 GCGM establishment-level + 4,000 MFS chain-level + 2,250 MFS establishment-level + 4,000 lodging chain-level + 3,100 lodging establishment-level + 14,750 SRE chain-level + 3,050 SRE establishment-level). Annualized over 3 years, this value yields 69,017 (= 207,052 records / 3 years) per year. We estimate that each nutrition analysis will require a burden of 15 minutes to produce each record. We estimate the total recordkeeping burden for the initial nutrition analysis to be 17,254.25 hours (= 69,017 records x 0.25 hours per record).

Recurring Nutrition Analysis

From Mintel Menu Insights data, we estimate that restaurant chains introduced, on average, 24 new menu items in 2009 (Ref. 47 of the final rule). Because the final requirements do not apply to temporary menu items, daily specials, and foods that are part of a customary market test, only a fraction of these items will need nutrition analysis. We estimate that existing restaurant chains or individual establishments would need new nutrition analysis for 25 percent of new standard menu items, or six new standard menu items per year. If in addition to these new standard menu items, chains need nutrition analysis on 6 reformulated standard menu items, there would be a total of 12 nutrition analyses per chain needed on an annual basis. Thus we estimate there will be 26,904 annual records associated with new or reformulated items of covered chains [= (1,151 restaurant chains + 691 GCGM chains + 50 MFS chains + 100 lodging chains + 250 SRE chains) x 12 menu items].

In addition we estimate that each year there will be the number of covered chains to increase in each category as companies expand. As discussed in the final RIA, each year there will be some existing non-covered chains that, through expansion of their business, will become subject to the rule's requirements (for example, a chain expanding from 19 to 20 locations). We estimate there will be 20 new restaurant chains, each with an average of 117 menu items; 5 new GCGM chains each with an average of 40 menu items; 3 new MFS chains each with an average of 80 menu items; 2 new lodging chains each with an average of 40 menu items; 5 new SRE chains each with an average of 59 menu items. Thus we estimate there will be 3,155 annual records [= (20 restaurants x 117 items) + (5 GCGM x 40 items) + (3 MFS x 80 items) + (2 lodging x 40 items) + (5 SRE x 59 items)] associated with nutrition analysis for new covered chains.

Based on data from FDA's Recordkeeping Cost Model, we estimate that it will take approximately 15 minutes per standard menu item for providing the information of nutrition analysis to FDA (Ref. 48 of the final rule). We estimate the total recurring recordkeeping burden for the nutrition analysis to be 7,515 hours [(26,899 records for new/reformulated standard menu items under existing chains + 3,155 records for items under new chains) x 0.25 hours per record].

Third Party Disclosure Burden

| Table 3.--Estimated Third Party Disclosure Burden | | | | | | |
|---|-----------------|-----------------------------------|--------------------------|-------------------------------|----------------|---------------------------------------|
| 21 CFR Part 101 | No. Respondents | No. of Disclosures per Respondent | Total Annual Disclosures | Average Burden per Disclosure | Total Hours | Total Operating and Maintenance Costs |
| Initial Burden (Annualized over 3 years) | | | | | | |
| §101.8(c)(2)(i)(A) Initial Nutrition Analysis | 69,017 | 1 | 69,017 | 4 | 276,068 | - |
| §101.8(c)(2)(i)(A) Initial Menu Replacement | 106,168 | 1 | 106,168 | 0.5 (30 minutes) | 53,084 | \$248,767,000 |
| §101.8(c)(2)(i)(A) Written Nutrition Information Chain-level | 1,632 | 1 | 1,632 | 3 | 4,896 | - |
| §101.8(c)(2)(i)(A) Written Nutrition Information Establishment-level | 18,673 | 1 | 18,673 | 0.5 (30 minutes) | 9,337 | - |
| Annual Burden | | | | | | |
| §101.8(c)(2)(i)(A) Recurring Nutrition Analysis | 30,054 | 1 | 30,054 | 4 | 120,216 | - |
| §101.8(c)(2)(i)(A) Recurring Menu Replacement | 700 | 1 | 700 | 0.5 (30 minutes) | 350 | \$529,000 |
| Total | | | | | 463,951 | \$249,296,000 |

Initial Nutrition Analysis

The first burden is the time and effort expended by restaurants and other retail food establishments to determine the nutrition content of their covered menu items, which we refer to as “Nutrition Analysis.” A nutrition analysis entails the burden of determining nutrition content for covered and voluntary establishment menus by analyzing the food product and summarizing the nutritional information results. Note that the recordkeeping portion of this burden was estimated in the previous subsection.

Our estimate for the annual number of the restaurant and similar retail food chains and individual establishments that will be burdened with initial nutrition analysis is identical to our estimate for the chains and establishments under the recordkeeping subsection. The total number of respondents estimated for the third-party disclosure burden of initial nutrition analysis is 207,052. Annualized over 3 years, this value becomes 69,017. We estimate that each nutrition analysis will require a burden of 4 hours (this estimate of 4 hours was used in the final RIA (Ref. 42 of the final rule)),

thus total burden for the initial nutrition analysis is 276,068 hours (207,052 records /3 years x 4 hours per record).

Recurring Nutrition Analysis

The second burden is the time and effort expended by restaurants and other retail food establishments in recurring nutrition analysis. As discussed in the recordkeeping subsection of this PRA, recurring nutrition analysis will be required for new and reformulated standard menu items. Our estimate for the annual number of the restaurant and similar retail food chains and individual establishments that will be burdened with recurring nutrition analysis is identical to our estimate for the chains and establishments under the recordkeeping subsection. The total number of respondents estimated for the third-party disclosure burden of recurring nutrition analysis is 30,054. We estimate that each nutrition analysis will require a burden of 4 hours (this estimate of 4 hours was used in the final RIA (Ref. 42 of the final rule)), thus total third party disclosure burden recurring nutrition analysis is 120,216 hours (30,054 records x 4 hours per record).

Initial Menu Replacement

The third burden is for the time expended by restaurants and similar retail food establishments to physically produce and install the menus, menu boards that include the new calorie declarations, which we refer to as “Calorie Declaration Signs.” As described in the final RIA (Ref. 42 of the final rule), chain retail food establishments will need to redesign and replace their existing menus and menu boards in order to comply with the final requirements. For full service restaurants and drinking places with only personal menus and no menu boards, this burden will be relatively low. Most menus are replaced frequently anyway as they wear out, are lost, or as prices and menu items change. For many of these establishments, the burden of updating menus to comply with the final requirements would be limited to design and associated administrative hours.

The longer lifespan of menu boards in limited-service eating places would likely require the redesign of menu/menu boards and the replacement of one or more menu boards. In addition, some chains would need to update self-serve and display signs. The number of menus that an establishment will keep on hand is highly variable. A full-service restaurant, where each order is placed using a menu, will need more than a quick-service establishment that uses menus just for takeout orders. The number of menus is also tied to the seating capacity of the restaurant, and whether the menu is laminated or paper. Because paper menus are more fragile and cheaper to print in bulk, an establishment may keep a large reserve in stock, whereas establishments using more durable and expensive laminated menus may only keep a few extra on hand. Estimates for the burden of updating menu boards, other major displays that serve as menus, such as electronic displays, or major materials needed to disclose calories for self-serve or displayed foods to comply with the final requirements, will vary widely across chains and establishments because of different menu board and display types.

As described in the RIA, we estimate that the average full-service restaurant establishment must discard and reprint one menu for each seat, plus 10 extra, for a total of 91 menus per restaurant each year. We estimate that GCGM stores have an average of two menu boards per establishment based on public comments that we received. We estimate that MFS and SRE establishments will each have an average of one menu board. Lodging establishments generally have menus instead of menu boards, and we estimate the menu replacement burden for establishments in the lodging sector to be

87 menu replacements per establishment. Since each covered and voluntarily registered establishment will need to replace menus and/or menu boards, we estimate this total value to be 318,505 (= 248,610 restaurants + 53,095 GCGM + 4,500 MFS + 6,200 lodging + 6,100 SRE). (In the previous calculation, 248,610 restaurants = 231,200 covered restaurants + 17,410 voluntary; and 53,095 GCGM = 50,600 covered + 2,495 voluntary.) Annualized over 3 years, this value becomes 106,168 (= 318,505 / 3 years). We estimate the labor burden for ordering new menus and menu boards to be 30 minutes (0.5 hours) per establishment. Thus the total burden for initial menu replacement is 53,084 hours per year. At an average wage (which includes an extra 50 percent to account for overhead costs and employee benefits) of \$30 per hour for managers across the covered industries, the labor burden comes to \$1,593,000 (= 53,084 hours x \$30 per hour). In the final RIA (Ref. 42 of the final rule), we estimated the total average costs associated with initial menu replacement to be \$250.36 million. This value takes into consideration costs of menu/menu board design, printing, and installation. Subtracting the labor costs of ordering new menus, \$1,593,000, from the total costs for initial menu replacement, \$250,360,000, yields total initial operating and maintenance costs of \$248,767,000.

Recurring Menu Replacement for New Chains

The fourth burden is for the time expended by new restaurants and similar retail food establishments to physically replace menus and menu boards that include the new calorie declarations. All restaurants and similar retail food chains that become covered as the number of their associated establishments grows beyond the coverage threshold of 20 will need to replace their menus and menu boards. We estimated in the final RIA (Ref. 42 of the final rule) that the annual number of new covered restaurants and similar retail food establishments is 700. Again, we estimate the labor burden for ordering new menus and menu boards to be 30 minutes (0.5 hours) per establishment. Thus the total annual burden for recurring menu replacement is 350 hours per year. At an average wage (which includes an extra 50 percent in overhead costs and employee benefits) of \$30 per hour for managers across the covered industries, the recurring labor burden comes to \$11,000 (= 350 hours x \$30 per hour). In the final RIA, we estimated the total average annual operating and maintenance costs associated with recurring menu replacement to be \$540,000. This value takes into consideration costs of menu/menu board design, printing, and installation. Subtracting the recurring labor costs of ordering new menus, \$11,000, from the total costs for recurring menu replacement of \$540,000, yields total recurring operating and maintenance costs of \$529,000.

Written Nutrition Information

The fifth burden is for the time expended by restaurants and similar retail food establishments to make written nutrition information available to customers upon request. The number of chains (and associated establishments) that do not already provide this information was estimated in the recordkeeping subsection under initial nutrition analysis, or 1,632 chains (503 covered restaurant + 38 voluntary restaurant + 660 covered GCGM + 31 voluntary GCGM + 50 covered MFS + 100 covered lodging + 250 covered SRE) and 18,673 establishments with establishment specific-menu items (10,866 covered restaurant + 818 voluntary restaurant + 5,060 covered GCGM + 249 voluntary GCGM + 450 covered MFS + 620 covered lodging + 610 covered SRE). We estimate the time it takes to provide written nutrition information at the chain level to be 3 hours per respondent. Since the average number of establishment-specific menu items is only five per establishment, we estimate the time it takes to provide written nutrition information at the establishment level (for those menu items that are specific only to the establishment) to be 30 minutes per respondent. Thus

the total burden hours for chain-level and establishment level written nutrition information disclosure are 4,896 and 9,336.5 hours, respectively. Therefore the total third party disclosure burden for the rule is 463,950.5 in annual hours with total operating and maintenance costs of \$249,296,000.

12b. Annualized Cost Burden Estimate

FDA estimates an initial cost burden of \$35,590 with a recurring cost burden of \$40,050. The analogous initial cost burden displayed in the third row of Table 2, \$75,640, 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 rates based on 2010 BLS Occupational Employment Statistics, we estimate the hourly wage rate for a non-manager to be \$15 (Ref. 9 of the final rule).

| 21 CFR Part 101 | Total Hours | Hourly Wage Rate | Total Respondent Costs |
|--|-------------|------------------|------------------------|
| Initial Burden (annualized over 3 years) | | | |
| § 101.8(d) Initial Registration | 7,118 | \$5.00 | \$35,590 |
| Annual Burden | | | |
| § 101.8(d) Registration Renewal | 2,670 | \$15.00 | \$40,050 |
| Total Burden Hours | 9,788 | | \$75,640 |

¹ 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 \$249,296,000, and include the costs of initial and recurring menu replacement as referenced in rows 3 and 8 of Table 3 (Third Party Disclosure Burden) above.

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 19191[2]) for this collection, FDA discontinued its approval authority for the original provisions found under OMB Control No. 0910-0665 upon its expiration in 2014. Therefore we are now 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.