FOOD & DRUG ADMINISTRATION:
Food Labeling Regulations

OMB Control No. 0910-0381

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection request supports food labeling regulations enforced by the United States Food and Drug Administration ("FDA" or "we"). Specifically, food labeling regulations require food producers to disclose to consumers and others specific information about themselves or their products on the label or labeling of their products. Related regulations require that food producers retain records establishing the basis for the information contained in the label or labeling of their products and provide those records to regulatory officials. Finally, certain regulations provide for the submission of food labeling petitions to FDA. Regulations governing food labeling may be found in parts 101, 102, 104, and 105 (21 CFR parts 101, 102, 104, and 105), and are issued under the authority of sections 4, 5, and 6 of the Fair Packaging and Labeling Act (the FPLA) (15 U.S.C. 1453, 1454, and 1455) and sections 201, 301, 402, 403, 409, 411, 701, and 721 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321, 331, 342, 343, 348, 350, 371, and 379e). Most of the regulations derive from section 403 of the FD&C Act, which provides that a food product shall be deemed to be misbranded if, among other things, its label or labeling fails to bear certain required information concerning the food product, is false or misleading in any particular, or bears certain types of unauthorized claims. The disclosure requirements and other collections of information in the regulations in parts 101, 102, 104, and 105 are necessary to ensure that food products produced or sold in the United States are in compliance with the labeling provisions of the FD&C Act and the FPLA.

Section 101.3 of our food labeling regulations requires that the label of a food product in packaged form bear a statement of identity (i.e., the name of the product), including, as appropriate, the form of the food or the name of the food imitated. Section 101.4 prescribes requirements for the declaration of ingredients on the label or labeling of food products in packaged form. Section 101.5 requires that the label of a food product in packaged form specify the name and place of business of the manufacturer, packer, or distributor and, if the food producer is not the manufacturer of the food product, its connection with the food product.

On August 29, 2016 (81 FR 59129), the Food and Drug Administration (FDA or we) issued a final rule entitled, "*Food Labeling; Technical Amendments*," revising 21 CFR Parts 1, 100, 101, and 104. As a result, section 101.105 (21 CFR 101.105) became section 101.7 (21 CFR 101.7). Section 101.7 specifies requirements for the declaration

of the net quantity of contents on the label of a food in packaged form and prescribes conditions under which a food whose label does not accurately reflect the actual quantity of contents may be sold, with appropriate disclosures, to an institution operated by a Federal, State or local government.

Section 101.108 provides for the submission to us of a written proposal requesting a temporary exemption from certain requirements of §§ 101.9 and 105.66 for the purpose of conducting food labeling experiments with our authorization.

Section 101.9 requires that nutrition information be provided for all food products intended for human consumption and offered for sale, unless an exemption in § 101.9(j) applies to the product. In particular, § 101.9(c)(2)(ii) requires that the amount of trans fatty acids present in a food must be declared on the nutrition label on a separate line immediately under the line for the declaration of saturated fat. Section 101.9(g)(9) provides that interested parties may submit to us requests for alternative approaches to nutrition labeling requirements. Finally, § 101.9(j)(18) provides that firms claiming the small business exemption from nutrition labeling must submit notice to us supporting their claim exemption. We developed Form FDA 3570 to assist small businesses in claiming the small business exemption from nutrition labeling. The form contains all the elements required by § 101.9(j)(18).

Section 101.10 requires that restaurants provide nutrition information, upon request, for any food or meal for which a nutrient content claim or health claim is made. Section 101.12(b) provides the reference amount that is used for determining the serving sizes for specific products, including baking powder, baking soda, and pectin. Section 101.12(e) provides that a manufacturer that adjusts the reference amount customarily consumed (RACC) of an aerated food for the difference in density of the aerated food relative to the density of the appropriate nonaerated reference food must be prepared to show us detailed protocols and records of all data that were used to determine the density-adjusted RACC. Section 101.12(g) requires that the label or labeling of a food product disclose the serving size that is the basis for a claim made for the product if the serving size on which the claim is based differs from the RACC. Section 101.12(h) provides for the submission of petitions requesting that we change the reference amounts defined by regulation.

Section 101.13 requires that nutrition information be provided in accordance with § 101.9 for any food product for which a nutrient content claim is made. Under some circumstances, § 101.13 also requires the disclosure of other types of information as a condition for the use of a nutrient content claim. For example, under § 101.13(j), if the claim compares the level of a nutrient in the food with the level of the same nutrient in another “reference” food, the claim must also disclose the identity of the reference food, the amount of the nutrient in each food, and the percentage or fractional amount by which the amount of the nutrient in the labeled food differs from the amount of the nutrient in the reference food. It also requires that when this comparison is based on an average of food products, this information must be provided to consumers or regulatory officials upon request. Section 101.13(q)(5) requires that restaurants document and provide to

appropriate regulatory officials, upon request, the basis for any nutrient content claims they have made for the foods they sell.

Section 101.14(d)(2) and (d)(3) provides for the disclosure of nutrition information in accordance with § 101.9 and, under some circumstances, certain other information as a condition for making a health claim for a food product. Section 101.15 provides that, if the label of a food product contains any representation in a foreign language, all words, statements, and other information required by or under authority of the FD&C Act to appear on the label must appear in both the foreign language and in English. Section 101.22 contains labeling requirements for the disclosure of spices, flavorings, colorings, and chemical preservatives in food products. Section 101.22(i)(4) sets forth disclosure and recordkeeping requirements pertaining to certifications for flavors designated as containing no artificial flavors. Section 101.30 specifies the conditions under which a beverage that purports to contain any fruit or vegetable juice must declare the percentage of juice present in the beverage and the manner in which the declaration is to be made.

Section 101.36 requires that nutrition information be provided for dietary supplements offered for sale, unless an exemption in § 101.36(h) applies. In particular, § 101.36(b)(2) requires that the amount of trans fatty acids present in dietary supplements must be declared on the nutrition label on a separate line immediately under the line for the declaration of saturated fat. Section 101.36(e) permits the voluntary declaration of the quantitative amount and the percent of Daily Value of a dietary ingredient on a "per day" basis in addition to the required "per serving" basis, if a dietary supplement label recommends that the dietary supplement be consumed more than once per day. Section 101.36(f)(2) cross-references the provisions in § 101.9(g)(9) for the submission to us of requests for alternative approaches to nutrition labeling requirements. Also, § 101.36(h)(2) cross-references the provisions in § 101.9(j)(18) for the submission of small business exemption notices. As noted above, we developed Form FDA 3570 to assist small businesses in claiming the small business exemption from nutrition labeling. The form contains all the elements required by § 101.36(h)(2). Section 101.36(e) permits the voluntary declaration of the quantitative amount and the percent of Daily Value of a dietary ingredient on a "*per day*" basis in addition to the required "*per serving*" basis, if a dietary supplement label recommends that the dietary supplement be consumed more than once per day.

Section 101.42 requests that food retailers voluntarily provide nutrition information for raw fruits, vegetables, and fish at the point of purchase, and § 101.45 contains guidelines for providing such information. Also, § 101.45(c) provides for the submission to us of nutrient databases and proposed nutrition labeling values for raw fruit, vegetables, and fish for review and approval.

Sections 101.54, 101.56, 101.60, 101.61, and 101.62 specify information that must be disclosed as a condition for making particular nutrient content claims. Section 101.67 provides for the use of nutrient content claims for butter, and cross-references requirements in other regulations for information declaration (§ 101.4) and disclosure of information concerning performance characteristics (§ 101.13(d)). Section 101.69

provides for the submission of a petition requesting that we authorize a particular nutrient content claim by regulation. Section 101.70 provides for the submission of a petition requesting that we authorize a particular health claim by regulation. Section 101.77(c)(2)(ii)(D) requires the disclosure of soluble fiber per serving in the nutrition labeling of a food bearing a health claim about the relationship between soluble fiber and a reduced risk of coronary heart disease. Section 101.79(c)(2)(iv) requires the disclosure of the amount of folate in the nutrition label of a food bearing a health claim about the relationship between folate and a reduced risk of neural tube defects.

Section 101.100(d) provides that any agreement that forms the basis for an exemption from the labeling requirements of section 403(c), (e), (g), (h), (i), (k), and (q) of the FD&C Act be in writing and that a copy of the agreement be made available to us upon request. Section 101.100 also contains reporting and disclosure requirements as conditions for claiming certain labeling exemptions (e.g., 101.100(h)).

Regulations in part 102 define the information that must be included as part of the statement of identity for particular foods and prescribe related labeling requirements for some of these foods. For example, § 102.22 requires that the name of a protein hydrolysate will include the identity of the food source from which the protein was derived.

Part 104, which pertains to nutritional quality guidelines for foods, cross-references several labeling provisions found in part 101.

Part 105 contains special labeling requirements for hypoallergenic foods, infant foods, and certain foods represented as useful in reducing or maintaining body weight.

We therefore request OMB approval of the information collection provisions found or referenced in 21 CFR Parts 101, 102, 104, and 105; Form FDA 3570, *Model Small Business Nutrition Labeling Exemption Notice*; and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The purpose of our food labeling requirements is to allow consumers to be knowledgeable about the foods they purchase. Nutrition labeling provides information for use by consumers in selecting a nutritious diet. Other information enables a consumer to comparison shop. Ingredient information also enables consumers to avoid substances to which they may be sensitive. Petitions or other requests submitted to us provide the basis for us to permit new labeling statements or to grant exemptions from certain labeling requirements. Recordkeeping requirements enable us to monitor the basis upon which certain label statements are made for food products and whether those statements are in compliance with the requirements of the FD&C Act or the FPLA.

The primary user of the information to be disclosed on the label or labeling of food products is the consumer that purchases the food product. Consumers will use the

information to assist them in making choices concerning their purchase of a food product, including choices related to substances that the consumer must avoid to prevent adverse reactions. This information also enables the consumer to determine the role of the food product in a healthful diet. Additionally, FDA intends to use the information to determine whether a manufacturer or other supplier of food products is meeting its statutory and regulatory obligations. Failure of a manufacturer or other supplier of food products to label its products in compliance with section 403 of the FD&C Act and parts 101, 102, 104, and 105 of FDA's food labeling regulations may result in a product being misbranded under the FD&C Act and the firm and the product subject to regulatory action.

The information submitted to FDA as a nutrient content claim or health claim petition will be used by the agency in reaching a finding as to whether the petition meets the requirements of the regulations for the issuance of regulations pertaining to nutrient content or health claims and thereby ensuring that the public health is safeguarded. The requirements in §§ 101.69 and 101.70 are those that FDA believes are necessary to fulfill the requirements of the FD&C Act. The consequences of not collecting the information required under these sections would be the inability of the agency to determine whether the petition meets the requirements of the regulation and whether the proposed claims are justified.

The information submitted to FDA for a nutrient content claim or health claim under the notification process will be used by FDA to assure that a Scientific Body of the United States Government or the National Academy of Sciences has published an authoritative statement which is currently in effect about the level of the nutrient to which the nutrient content claim refers or about the relationship between the nutrient and the disease or health related condition to which the health claim refers, and that the claim is an accurate representation of that statement.

The information collections that will be reported to FDA under the provisions of §§ 101.9(j)(18) and 101.36(h)(2) will be from small businesses for the purpose of claiming an exemption from nutrition labeling for low-volume food products. Under section 403(q)(5)(E) of the FD&C Act, a low-volume food product is exempt from the requirements for nutrition labeling if it is the subject of a notice from a small business claiming the exemption provided by the Nutrition Labeling and Education Act Amendments of 1993. Those food products that are not the subject of such a notice are not exempt from the mandatory nutrition labeling requirements of section 403 (q) of the FD&C Act unless the food qualifies for another exemption. Section 403(q)(5)(E) of the FD&C Act does not require that the information in a notice claiming exemption be reviewed by FDA for the exemption to be in effect. However, FDA does review the information in each notice to determine whether it meets the requirements for the notice established in section 403(q)(5)(E)(iii) of the FD&C Act. FDA provides the information on the identity of firms submitting notices claiming exemption to its field personnel and to State enforcement agencies by posting the names and addresses of the firms on a website maintained by the agency.

Information in petitions submitted under the provisions of § 101.12(h) will be used by the agency in reaching a conclusion as to whether a new reference amount should be established or an existing reference amount should be amended. The consequence of not having this information is that FDA would be restricted in obtaining the information necessary to amend or add to the regulation on reference amounts.

Information submitted to FDA in response to the provisions for alternative approaches contained in §§ 101.9(g)(9) and 101.36(f)(2) is used by FDA to determine whether such alternative approaches would be consistent with the requirements for nutrition labeling in section 403(q) of the FD&C Act. The consequences of not having this information would be a reduced flexibility of the manufacturer to use alternative approaches for complying with the requirements of section 403(q) of the FD&C Act for the nutrition labeling of food products.

Data generated by the food labeling experiments permitted under § 101.108 may form the basis for a citizen's petition to amend the existing food labeling regulations. The data could also be useful to FDA for evaluating whether changes in current food labeling requirements are warranted, and for developing alternative labeling formats that may be useful to consumers and manufacturers. The extent of the collection of information is determined by the firm proposing the labeling experiment, and is of benefit to this firm. However, the labeling changes proposed by a firm could not be implemented without supporting information favoring the proposed changes.

Description of Respondents: Respondents to this information collection are manufacturers, packers, and distributors of food products. Because of the existence of exemptions and exceptions, not all of the requirements apply to all food producers or to all of their products. Some of the regulations affect food retailers, such as supermarkets and restaurants. Respondents include the private sector (including for-profit businesses, not-for-profit institutions and farms).

3. Use of Improved Information Technology and Burden Reduction

The regulations in parts 101, 102, 104, and 105 do not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by firms. Companies are free to use whatever forms of information technology may best assist them in developing notifications or meeting labeling requirements for food. FDA has developed a web-based data entry system so small businesses may electronically claim exemption from the requirements for nutrition labeling. FDA estimates that ninety percent (90%) of the respondents will use electronic means to submit the request for exemption.

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

   FDA estimates that approximately ten percent (10%) of the respondents are small businesses. The requirements are the minimum requirements for complying with the provisions of the FD&C Act. In most cases, the information that is required to be disclosed or submitted to the agency is information that is available to a firm, including a small business, as a normal course of its doing business. Small businesses may claim exemption from the requirements for nutrition labeling under the provisions of 21 CFR 101.9(j)(18) and 101.36(h)(2). FDA aids small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the scientific and administrative 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

   Data collection occurs occasionally. There are no consequences to Federal program or policy activities if the information is collected less frequently. As noted above, failure of a firm to comply with the requirements for disclosure of the information on the labels or labeling of its food products may result in those products being misbranded under section 403 of the FD&C Act and the products and the firm subject to regulatory action.

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), in the Federal Register of December 30, 2016 (81 FR 96462), we published a 60-day notice requesting public comment on the proposed collection of information. FDA received two comments. One comment was not related to the Paperwork Reduction Act and is therefore not discussed. The second comment underscored the importance of food labeling and offered general support of the information collection.

9. Explanation of Any Payment or Gift to Respondents

   This information collection does not provide for payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Information submitted to FDA under the food labeling regulations may contain trade secret and commercial confidential information. Only information that is releasable under the agency's regulations in 21 CFR part 20 would be released to the public. This information is also safeguarded by Section 301(j) of the FD&C Act and would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)).

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally 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:

Table 1 – Estimated Annual Reporting Burden

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
101.9(j)(18) and 101.36(h)(2); procedure for small business nutrition labeling exemption notice using *Form FDA 3570*	10,000	1	10,000	8	80,000
101.12(h); petitions to establish or amend a RACC	5	1	5	80	400
101.69; petitions for nutrient content claims	3	1	3	25	75
101.70; petitions for health claims	5	1	5	80	400
101.108; written proposal for requesting temporary exemptions from certain regulations for the purpose of conducting food labeling experiments	1	1	1	40	40
TOTAL			10,014		80,915

Table 2 – Estimated Annual Recordkeeping Burden

21 CFR Section; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
101.7(t); recordkeeping pertaining to disclosure requirements for food not accurately labeled for quantity of contents	100	1	100	1	100
101.12(e); recordkeeping to document the basis for density-adjusted RACC	25	1	25	1	25
101.13(q)(5); recordkeeping to document the basis for nutrient content claims	300,000	1.5	450,000	0.75	337,500
101.14(d)(2); recordkeeping to document nutrition information related to health claims for food products	300,000	1.5	450,000	0.75	337,500
101.22(i)(4); recordkeeping to document supplier certifications for flavors designated as containing no artificial flavors	25	1	25	1	25
101.100(d)(2); recordkeeping pertaining to agreements that form the basis for an exemption from the labeling requirements of section 403(c), (e), (g), (h), (i), (k), and (q) of the FD&C Act	1,000	1	1,000	1	1,000
TOTAL			901,150		676,150

Table 3– Estimated Annual Third Party Disclosure Burden

21 CFR Section; Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Avg. Burden per Disclosure	Total Hours
101.3, 101.22, 102 and 104; statement of identity labeling requirements	25,000	1.03	25,750	.5	12,875
101.4, 101.22, 101.100, 102, 104 and 105; ingredient labeling requirements	25,000	1.03	25,750	1	25,750
101.5; requirement to specify the name and place of business of the manufacturer, packer, or distributor and, if the food producer is not the manufacturer of the food product, its connection with the food product	25,000	1.03	25,750	0.25	6,438
101.9, 101.13(n), 101.14(d)(3), 101.62, and 104; labeling requirements for disclosure of nutrition information	25,000	1.03	25,750	40	103,000
101.9(g)(9) and 101.36(f)(2); alternative means of compliance permitted	12	1	12	4	48

21 CFR Section; Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Avg. Burden per Disclosure	Total Hours
101.10; requirements for nutrition labeling of restaurant foods	300,000	1.5	450,000	0.25	112,500
101.12(b); RACC for baking powder, baking soda and pectin	29	2.3	67	1	67
101.12(e); adjustment to the RACC of an aerated food permitted	25	1	25	1	25
101.12(g); requirement to disclose the serving size that is the basis for a claim made for the product if the serving size on which the claim is based differs from the RACC	5,000	1	5,000	1	5,000
101.13(d)(1) and 101.67; requirements to disclose nutrition information for any food product for which a nutrient content claim is made	200	1	200	1	200
101.13(j)(2), 101.13(k), 101.54, 101.56, 101.60, 101.61, and 101.62; additional disclosure required if the nutrient content claim compares the level of a nutrient in one food with the level of the same nutrient in another food	5,000	1	5,000	1	5,000
101.13(q)(5); requirement that restaurants disclose the basis for nutrient content claims made for their food	300,000	1.5	450,000	0.75	337,500
101.14(d)(2); general requirements for disclosure of nutrition information related to health claims for food products	300,000	1.5	450,000	0.75	337,500
101.15; requirements pertaining to prominence of required statements and use of foreign language	160	10	1,600	8	12,800
101.22(i)(4); supplier certifications for flavors designated as containing no artificial flavors	25	1	25	1	25
101.30 and 102.33; labeling requirements for fruit or vegetable juice beverages	1,500	5	7,500	1	7,500
101.36; nutrition labeling of dietary supplements	300	40	12,000	4.025	48,300
101.42 and 101.45; nutrition labeling of raw fruits, vegetables, and fish	1,000	1	1,000	0.5	500
101.45(c); databases of nutrient values for raw fruits, vegetables, and fish	5	4	20	4	80
101.79(c)(2)(i)(D); disclosure requirements for food labels that contain a folate/neural tube defect health claim	1,000	1	1,000	0.25	250

21 CFR Section; Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Avg. Burden per Disclosure	Total Hours
101.79(c)(2)(iv); disclosure of amount of folate for food labels that contain a folate/neural tube defect health claim	100	1	100	0.25	25
101.100(d); disclosure of agreements that form the basis for exemption from the labeling requirements of section 403(c), (e), (g), (h), (i), (k), and (q) of the FD&C Act	1,000	1	1,000	1	1,000
101.7 and 101.100(h); disclosure requirements for food not accurately labeled for quantity of contents and for claiming certain labeling exemptions	25,000	1.03	25,750	0.5	12,875
TOTAL			1,513,299		1,029,258

The estimated annual reporting, recordkeeping, and third party disclosure burdens reflected in Tables 1-3 above are based on our informal communications with industry and our experience with the information collection. Also, while section 101.108 was promulgated to provide a petition procedure for certain food labeling exemptions, no such petitions have been received in the recent past and we therefore provide an estimate of 1 to reserve approval of any future collection under this part.

12b. Annualized Cost Burden Estimate

FDA estimates that the total annualized cost burden to respondents associated with the requirements of parts 101 of the regulations to be approximately $162,269,581.32. FDA estimates a respondent's average wage to be commensurate to that of a Federal government employee at the GS-13/Step-1 rate for the year 2017, $45.42 per hour. To account for overhead, this cost is increased by 100 percent, making the estimated cost burden to the respondent $90.84 per hour. Using these figures, the agency estimates the cost burden for reporting to be $7,350,318.60 (80,915 hours x $90.84 per hour), the burden hour cost for recordkeeping to be $61,421,466 (676,150 hours x $90.84 per hour); and, the cost burden for third-party disclosure to be $93,497,796.72 (1,029,258 hours x $90.84 per hour), for a total annualized burden hour cost of $162,269,581.32.

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Reporting	80,915	$90.84	$7,350,318.60
Recordkeeping	676,150	$90.84	$61,421,466.00
Third Party Disclosure	1,029,258	$90.84	$93,497,796.72
Total			$162,269,581.32

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 estimates that the cost to the Federal government to inspect firms and to collect and analyze samples to determine compliance with requirements for dietary supplements to be approximately 14.2 person years. Based on an average person-year cost of approximately $100,000 and an allowance of $80,000 for overhead, the agency estimates that this amount of time translates to a cost to the Federal Government of $2,556,000 per year. FDA further estimates that as much as one person-year at an estimated cost of $180,000 would be required to respond to violations involving dietary supplements.

Based on its experience, FDA estimates that it will utilize annually 14.7 person years to inspect firms and collect and analyze samples of conventional foods to determine compliance with the various food labeling provisions. Using on an average person-year cost of approximately $100,000 and including an allowance of $80,000 for overhead, FDA estimates that this amount of time translates to a cost to the Federal government of approximately $2,646,000 per year. FDA also estimates that an additional one person year at an estimated cost of $180,000 would be required to respond to violations involving conventional foods.

Six of the regulations contain provisions for the submission of petitions or notices to FDA. FDA estimates that a total of over 7,100 hours would be expended in the review of these submissions. At an estimated rate for a GS-13, Step 1, with overhead estimated to be equal to the hourly rate, the hourly cost for the review and evaluation of the various submissions is estimated to be approximately $90.84 per hour for a total estimated cost to the Federal Government of more than $644,964. FDA estimates that the total cost to the Federal Government of the provisions contained in this information collection to be approximately $6,206,964.

15. Explanation for Program Changes or Adjustments

This information collection reflects editorial adjustments only. As previously noted, by technical amendment on August 29, 2016, 21 CFR part 101.105 became 21 CFR part 101.7, however there was no change in burden to the underlying requirement regarding declaration of net quantity of product contents. In addition, we have revised the IC list appearing at www.reginfo.gov by consolidating the previously itemized regulatory provisions into reporting, recordkeeping, and third party disclosure categories. We believe this will assist the reader by more easily identifying the summary of cumulative fluctuations for the collection. At the same time, readers may still view estimated burden associated with individual provisions by referring to the agency's 60-day and 30-day

notices and in the burden tables found in Q.12: *Estimates of Annualized Burden Hours and Costs* of this supporting statement.

16. Plans for Tabulation and Publication and Project Time Schedule

The information from this collection will not be published.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Display of OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.