

**Food Labeling Regulations**  
**OMB Control No. 0910-0381**  
**SUPPORTING STATEMENT, Part A**

**A. Justification**

**1. Circumstances Making the Collection of Information Necessary**

Our 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 us. We issued our food labeling regulations under parts 101, 102, 104, and 105 (21 CFR parts 101, 102, 104, and 105) 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 these 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.

This is a revision request in which the agency seeks to extend the current approvals listed and discussed below, and to incorporate the burden previously approved under OMB control numbers 0910-0595 and 0910-0395. The latter collections were approved in conjunction with their associated rulemaking and have subsequently expired. Because we must continue to collect the information required by our regulations, we are seeking to consolidate, where possible, our food labeling information collections.

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.

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)).

Section 101.105 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.

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 in part 101 but contains no separate information collection requirements.

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

We request the extension of OMB approval for the collection of information requirements in the following regulations and forms: 21 CFR Parts 101, 102, 104, and 105 and Form FDA 3570, Model Small Business Nutrition Labeling Exemption Notice, that small businesses may use to claim the small business exemption from nutrition labeling.

## **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 act and parts 101, 102, 104, and 105 of FDA's food labeling regulations may result in a product being misbranded under the 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 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 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 act unless the food qualifies for another exemption. Section 403(q)(5)(E) of the 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 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 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 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 (available at: <https://info1.cfsan.fda.gov/nle/client/login.cfm>). 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**

No duplication of Federal regulations concerning the requirements for the labeling of food products is likely because of the clear Congressional authorization that FDA promulgate regulations pertaining to the labeling of foods as opposed to the jurisdiction of the U.S. Department of Agriculture (meats and poultry) and the Federal Trade Commission (advertising).

#### **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 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 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 November 1, 2013 (78 FR 65663), we published a 60-day notice requesting public comment on the proposed collection of information. Several comments were received in response to the notice. Many were generally supportive of the necessity of our food labeling regulations. Other comments were beyond the scope of the four collection of information topics on which the notice solicits comments and are therefore not discussed in this document.

A number of comments referenced our Federal Register notice published on November 8, 2013 (78 FR 67169) ("the November 8, 2013 notice") announcing the tentative determination that

partially hydrogenated oils (PHOs) are no longer "generally recognized as safe" (GRAS). Some comments supported this determination while others opposed it. Supportive comments suggested that labels should be placed on food packaging warning consumers of the negative health effects of the trans fatty acid component of PHOs. FDA notes that it does not require warning labels on food containing trans fatty acid, but we agree that trans fatty acid content should be provided in the nutrition labeling of food. In the Federal Register of July 11, 2003 (68 FR 41434), we issued a final rule ("the July 2003 final rule") amending our nutrition labeling regulations to require declaration of the trans fatty acid content of food in the nutrition label of conventional foods and dietary supplements (21 CFR 101.9(c)(2)(ii)). This requirement was effective January 1, 2006. The November 8, 2013 notice seeks comments on our preliminary determination that PHOs are not GRAS and we have submitted comments relevant to this topic to that docket as well. If FDA makes a final determination that PHOs are not GRAS, the food industry would be required to phase out the use of PHOs in food over time, not place warning labels on their food products.

**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 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 Third Party Disclosure Burden <sup>1</sup>

21 CFR Section	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

21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Avg. Burden per Disclosure	Total Hours
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
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



21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Avg. Burden per Disclosure	Total Hours
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
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
101.105 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					1,029,258

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

Table 2.--Estimated Annual Recordkeeping Burden<sup>1</sup>

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
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
101.105(t); recordkeeping pertaining to disclosure requirements for food not accurately labeled for quantity of contents	100	1	100	1	100
<b>Total</b>					<b>676,150</b>

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

Table 3.--Estimated Annual Reporting Burden<sup>1</sup>

21 CFR Section/ Form No.	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
<b>Total</b>					<b>80,915</b>

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

The estimated annual third party disclosure, recordkeeping and reporting burdens are based on our communications with industry and our knowledge of and experience with food labeling and the submission of petitions and requests to us.

As noted, we are revising this collection to include previously approved third party disclosure burdens associated with the requirement to declare the amount of trans fatty acids present in a food, including dietary supplements. The third party disclosure burden hours formerly associated with OMB Control Number 0910-0515 (collection titled, “Food Labeling: Trans Fatty Acids in Nutrition Labeling”) are represented by the citation to § 101.9 on line 4 of Table 1 and the citation to § 101.36 on line 17 of Table 1. For this revision, we have not added burden hours to line 4 or line 17 of Table 1 because, based on our experience with food labeling, the 40 hours estimated for meeting the labeling requirements of § 101.9 and the 4 hours estimated for meeting the labeling requirements of § 101.36 are appropriate estimates of the total time it takes a respondent to meet our requirements for nutrition labeling in §§ 101.9 and 101.36.

We are also revising this collection to include previously approved third party disclosure burdens associated with 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. The third party disclosure burden hours formerly associated with OMB Control Number 0910-0395 (collection titled, “Food Labeling: Nutrition Labeling of Dietary Supplements on a ‘Per Day’ Basis”) are represented by the citation to § 101.36 on line 17 of Table 1 and the addition of 300 hours to our previous estimate of 48,000 hours. For this revision, we added 300 burden hours to line 17 of Table 1 because voluntary labeling on a “per day” basis is in addition to the required “per serving” basis. We estimate that “per day” information would generally be placed on at most 10 percent of the estimated 12,000 disclosures, for a total of 1,200 annual disclosures, and that a respondent will spend 15 minutes (0.25 hours) per disclosure, for a total of 300 hours. Thus, the total estimated burden on line 17 of Table 1 is 48,300 hours and average burden per disclosure on line 17 of Table 1 has been increased from 4.0 to 4.025 hours, to represent an averaging of the burden hours across all of the estimated 12,000 disclosures.

We expect that the burden hours for submissions under § 101.108 will be insignificant. Section 101.108 was originally promulgated to provide a procedure whereby we could grant exemptions from certain food labeling requirements. Exemption petitions have infrequently been submitted in the recent past; none have been submitted since publication on January 6, 1993, of the final regulations implementing section 403(q) and (r) of the FD&C Act. Thus, in order to maintain OMB approval of § 101.108 to accommodate the possibility that a food producer may propose to conduct a labeling experiment on its own initiative, we estimate that we will receive one or fewer submissions under § 101.108 in the next three years.

*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.

## **12 b. Annualized Cost Burden Estimate**

FDA estimates that the total annualized burden hour cost to respondents associated with the requirements of parts 101, 102, 104, and 105 of the regulations to be approximately

\$152,409,078.36. FDA estimates a respondent's average wage to be that of a Federal government employee at the GS-13/Step-1 rate for the year 20013, \$42.66 per hour. To account for overhead, this cost is increased by 100 percent, making the estimated burden hour cost to the respondent \$85.32 per hour. Using these figures, the agency estimates the burden hour cost for third party disclosure to be \$87,816,292.56 (1,029,258 hours x \$85.32 per hour); the burden hour cost for recordkeeping to be \$57,689,118 (676,150 hours x \$85.32 per hour); and, the burden hour cost for reporting to be \$6,903,667.80 (80,915 hours x \$85.32 per hour), for a total annualized burden hour cost of \$152,409,078.36.

### **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**

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 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 estimates that an additional one person year at an estimated cost of \$180,000 would be required to respond to violations involving conventional foods.

In the Federal Register of September 23, 1997, FDA published a final rule entitled "Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements; Compliance Policy Guide, Revocation" in which it estimated the cost to the Federal government to inspect firms and to collect and analyze samples to determine compliance with the newly established 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 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.

Six of the regulations contain provisions for the submission of petitions or notices to FDA. FDA estimates that a total of over 7100 hours would be expended in the review of these submissions. At an estimated rate for a GS-13, 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 \$64 per hour for a total estimated cost to the Federal Government of more than \$454,400. FDA estimates that the total cost to the Federal Government of the provisions contained in this information collection to be approximately \$6,016,400.00.

### **15. Explanation for Program Changes or Adjustments**

This ICR adds two previously approved collections: OMB Control No. 0910-0395 gave FDA approval for requiring "per day" labeling information; and OMB Control No. 0910-0515 gave the agency approval for declaring a product's trans-fat content. These provisions may be found at 21 CFR part 101 (food labeling). Although the agency intended to include these into the

instant collection, 0910-0381, we did not do so before their approval terms had expired. However, to account for the burden associated with these collections the agency made adjustments to one of the thirty-four individual information collections. This resulted in an overall increase of **300** burden hours for a total of **1,786,323** burden hours. The agency also made an adjustment to a second individual collection after noting a typographical error. Although the agency included 25,750 as the number of annual responses for the individual IC, the number 2,575 is what was inadvertently recorded at OMB. To correct this error, the agency added the difference of **23,175** annual responses for a total of **2,424,463** annual responses.

A breakdown of these adjustments is as follows:

<i>Individual Information Collection from Third Party Disclosure Table</i>	<i>Annual Responses</i>	<i>Hourly Burden</i>
IC #15: 21 CFR §§101.9, 101.13(n), 101.14(d)(3), 101.62, and 104; labeling requirements for disclosure of nutrition information	23175	0
IC #27: 21 CFR §101.36 nutrition labeling of dietary supplements	0	300
Overall increase	<b>23175</b>	<b>300</b>

Our estimates for the other ICs in this collection remain unchanged.

**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**

FDA has no reason for not displaying the OMB approval date.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.