FOOD LABELING REGULATIONS

OMB No. 0910-0381

SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Section 403 (21 U.S.C. 343) of the Federal Food, Drug, and Cosmetic Act (the act) establishes requirements that the label or labeling of a food product must meet so that it is not misbranded and subject to regulatory action. Certain of the provisions of section 403 require that food producers disclose information about themselves or their products on the labels or labeling of their products. Section 403(e) requires that the label disclose the name and place of business of the food producer and an accurate statement of the quantity of contents. Section 403(g) requires that the label for a food for which a definition and standard of identity has been prescribed by regulation must contain, as required by regulations, the common names of optional ingredients. Section 403(h) requires that the label of a food for which a standard of quality or a standard of fill has been prescribed by regulations, and its quality or fill falls below the standard of quality or fill, bear a statement that it falls below such standard. Section 403(i) requires that the label of a food product bear the common or usual name of the product, disclose the names of the ingredients used in producing the food, and disclose the amount of fruit or vegetable juice contained in the food if it is a beverage containing fruit or vegetable juice. Section 403(j) requires that the label of a food represented for special dietary uses must contain such information concerning its vitamin, mineral, and other dietary properties as prescribed by regulation. Section 403(q) requires that the label or labeling for a food intended for human consumption contain nutrition information. Section 403(r) provides that a health claim or nutrient content claim may be made only if it is authorized in a regulation or by action of the statute and provides for both a petition or notification process whereby new claims are authorized. FDA has issued various regulations in parts 101, 102, 104, and 105 (21 CFR parts 101, 102, 104, and 105) that also require food producers to disclose certain information on the labels of their food products. Failure of a food producer to comply with the provisions of section 403 of the act or of parts 101, 102, 104, or 105 would result in the specific product and the producer being subject to regulatory action.

FDA regulations in parts 101, 102, 104, and 105 (21 CFR parts 101, 102, 104, and 105) require food producers to disclose to consumers and others specific information about themselves or their products on the label or labeling of their products. These regulations were 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 of sections 201, 301, 402, 403, 409, and 701 of the act (21 U.S.C. 321, 331, 342, 348, and 371). Most of the regulations in Parts 101, 102, 104, and 105 derive from the requirements of section 403 of the act, which provides that a food product shall 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. Additionally, FDA has issued regulations among parts 101, 102, 104, and 105 that require that food producers retain records relative to the information contained in the label or labeling of their products and provide those records to regulatory officials. Finally, certain of the regulations issued by the agency provide for the submission of petitions to FDA.

Section 101.3 of FDA's 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 the 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. Section 101.9(g)(9) provides for the submission to FDA of requests for alternative approaches to nutrition labeling requirements. Finally, § 101.9(j)(18) provides for the submission to FDA of notices from firms claiming the small business exemption from nutrition labeling. FDA has 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 FDA 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 to FDA to request changes in the reference amounts defined by regulation.

Section 101.13 requires that nutrition information be provided in accordance with the provisions of § 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 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 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 reporting 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. Section 101.36(f)(2) cross-references the provisions in § 101.9(g)(9) for the submission to FDA 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, FDA has 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 101.42 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 of nutrient data and proposed nutrition labeling values for raw fruit, vegetables, and fish to FDA 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 FDA authorize a particular nutrient content claim by regulation. Section 101.70 provides for the submission of a petition requesting that FDA 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 act be in writing and that a copy of the agreement be made available to FDA upon request. Section 101.100 also contains reporting and disclosure requirements as conditions for claiming certain labeling exemptions.

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 FDA 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 FDA 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.

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 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.

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).

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

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).

6. Consequences of Collecting the Information Less Frequently

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.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), on July 15, 2009 (74 FR 34353), a 60-day notice for public comment was published in the Federal Register. FDA did not receive any comments responsive to the comment request in the notice.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment 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 any questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Description of Respondents: Respondents to this information collection are manufacturers, packers, and distributors of food products. Some of the regulations affect food retailers, such as supermarkets and restaurants.

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

Table 1. – Estimated Annual Third Party Disclosure Burden [1]

21 CFR Section	No. of Respondents	Annual Frequency of Disclosure	Total Annual Disclosures	Hours per Disclosures	Total Hours
101.3, 101.22, 102 and 104	25,000	1.03	25,750	.5	12,875
101.4, 101.22, 101.100, 102, 104 and 105	25,000	1.03	25,750	1	25,750
101.5	25,000	1.03	25,750	0.25	6,438
101.9, 101.13(n), 101.14(d)(3), 101.62, and 104	25,000	1.03	25,750	40	103,000
101.9(g)(9 and 101.36(f)(2)	12	1	12	4	48
101.10	300,000	1.5	450,000	0.25	112,500
101.12(b)	29	2.3	67	1	67
101.12(e)	25	1	25	1	25
101.12(g)	5,000	1	5,000	1	5,000
101.13(d)(1) and 101.67	200	1	200	1	200
101.13(j)(2), 101.13(k), 101.54, 101.56, 101.60, 101.61, and 101.62	5,000	1	5,000	1	5,000
101.13(q)(5)	300,000	1.5	450,000	0.75	337,500
101.14(d)(2)	300,000	1.5	450,000	0.75	337,500
101.15	160	10	1,600	8	12,800
101.22(i)(4)	25	1	25	1	25
101.30 and 102.33	1,500	5	7,500	1	7,500
101.36	300	40	12,000	4	48,000
101.42 and 101.45	1,000	1	1,000	0.5	500

101.45(c)	5	4	20	4	80
101.79(c)(2)(i)(D)	1,000	1	1,000	0.25	250
101.79(c)(2)(iv)	100	1	100	0.25	25
101.100(d)	1,000	1	1,000	1	1,000
101.105 and 101.100(h)	25,000	1.03	25,750	0.5	12,875
Total					1,028,958

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

Table 2.--Estimated Annual Recordkeeping Burden[1]					
21 CFR Section	No. of Record-keepers	Annual Frequency per Record-keeping	Total Annual Records	Hours per Record	Total Hours
101.12(e)	25	1	25	1	25
101.13(q)(5)	300,000	1.5	450,000	0.75	337,500
101.14(d)(2)	300,000	1.5	450,000	0.75	337,500
101.22(i)(4)	25	1	25	1	25
101.100(d)(2)	1,000	1	1,000	1	1,000
101.105(t)	100	1	100	1	100
Total					676,150

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

Table 3.--Estimated Annual Reporting Burden[1]							
21 CFR Section/ Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours		
101.9(j)(18) and 101.36(h)(2) Form FDA 3570	10,000	1	10,000	8	80,000		
101.12(h)	5	1	5	80	400		
101.69	3	1	3	25	75		
101.70	5	1	5	80	400		
101.108	1	1	1	40	40		
Total					80,915		

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

The estimated annual reporting and recordkeeping burdens are based on agency communications with industry and FDA's knowledge of and experience with food labeling and the submission of petitions and requests to the agency. Where an agency regulation implements an information collection requirement in the act or the FPLA, only any additional burden attributable to the regulation has been included in FDA's burden estimate.

FDA expects that the burden hours for submissions under § 101.108 will be insignificant. Section 101.108 was originally promulgated to provide a procedure whereby FDA 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 act. FDA is retaining § 101.108 in its regulations for the possibility that a food producer may propose to conduct a labeling experiment on its own initiative. At this time, however, FDA considers this possibility sufficiently unlikely that the hour burden may be considered to be insignificant.

No burden has been estimated for those requirements where the information to be disclosed is information that has been supplied by FDA. Also, no burden has been estimated for that information that is disclosed to third parties as a usual and customary part of a food producer's normal business activities. Under 5 CFR 1320(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

Estimated Annualized Cost for the Burden Hours

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 $120,905,514.20.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 2009, $33.84 per hour. To account for overhead, this cost is increased by 100 percent, making the estimated burden hour cost to the respondent $67.68 per hour. Using these figures, the agency estimates the burden hour cost for third party disclosure to be $69,667,355 (1,029,364 hours x $67.68 per hour); the burden hour cost for recordkeeping to be $45,761,832 (676,150 hours x $67.68 per hour); and, the burden hour cost for reporting to be $5,476,327.20 (80,915 hours x $67.68 per hour), for a total annualized burden hour cost of $120,905,514.20.

13. Estimates of Other Total Annual Costs to Respondents and Recordkeepers

There are no capital costs or operating and maintenance costs associated with this collection. An error correction is been acknowledged regarding O & M cost,with this ICR renewal request. There were no O & M cost(s) associated with the petitions for " Health Claims ," 21CFR 101.70, and petitions for "Reference Amounts' 21 CFR 101.12 (h). Thus this error regarding that cost has been deleted with this ICR submission.

14. Annualized Cost to the Federal Government

In FDA's field compliance program for FY-1999, FDA utilized 14.7 person years to inspect firms and collect and analyze samples of conventional foods to determine compliance with the various food labeling provisions. Based 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.

15. Explanation for Program Changes or Adjustments

The burden has not changed from the burden shown in the current inventory. However, as now required, 1,028,958 burden hours that were previously reported as reporting burdens are now reported as third party disclosure burdens. In addition, there is a one hour increase that corrects an error in the previous submission. The one hour increase is due to the burden for 101.12(b). In 2007, the burden hours were incorrectly calculated as 66 hours. The correct calculation is 29 x 2.3 = 67, not 66. This supporting statement corrects that error, thereby adding one hour to the total.

16. Plans for Tabulation and Publication and Project Time Schedule

The agency has no plans for publication of information from this information collection.

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

N/A.