

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA2009N0296]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Labeling Regulations

AGENCY:

Food and Drug Administration, HHS.

ACTION:

Notice.

SUMMARY:

The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES:

Fax written comments on the collection of information by [insert date 30 days after date of publication in the Federal Register].

ADDRESSES:

To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 2023957285, or e-mailed to oir-a_submission@omb.eop.gov. All comments should be identified with the OMB control number 09100381. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food Labeling Regulations 21 CFR Parts 101, 102, 104, and 105 (OMB Control Number 09100381) Extension

FDA 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. FDA's food labeling regulations under parts 101, 102, 104, and 105 (21 CFR parts 101, 102, 104, and 105) 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 under sections 201, 301, 402, 403, 409, 411, 701, and 721 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321, 331, 342, 343, 348, 350, 371, and 379e). Most of these regulations derive from section 403 of the 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 act and the FPLA.

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 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) also provides for the submission to FDA of requests for alternative approaches to nutrition labeling. 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 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.

Sections 101.14(d) (2) and (d) (3) provide 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 shall appear thereon 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 flavor. 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 102.33 specifies the common or usual name for beverages that contain fruit or vegetable juice.

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. Also, 101.36(h) (2) cross-references the provisions in 101.9(j) (18) for the submission of small business exemption notices. As noted previously, 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 bases 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 ingredient 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 the amount 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 per serving in the nutrition labeling 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 (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 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's 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 shall 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.

The disclosure and other information collection requirements in the previously mentioned regulations are placed primarily upon 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.

The purpose of the 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 FDA provide the basis for the agency to permit new labeling statements or to grant exemptions from certain labeling requirements. Recordkeeping requirements enable FDA 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 act or the FPLA.

In the Federal Register of July 15, 2009 (74 FR 34353), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received on this information collection.

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

<GPOTABLE COLS="6" OPTS="L2,nj,i1" CDEF="x130,16,16,16,16,16">

Table 1. Estimated Annual Reporting Burden1

21 CFR Section and Part/Form No.

No. of Respondents

Annual Frequency per Response

Total Annual
Responses

Hours per
Response

Total Hours

<ROW RUL="s,&qdrt;">101.3, 101.22, 102 and 104
25,000
1.03
25,750
.5
12,875

<ROW RUL="s,&qdrt;">101.4, 101.22, 101.100, 102, 104 and 105
25,000
1.03
25,750
1
25,750

<ROW RUL="s,&qdrt;">101.5
25,000
1.03
25,750
0.25
6,438

<ROW RUL="s,&qdrt;">101.9, 101.13(n), 101.14(d)(3), 101.62, and 104
25,000
1.03
25,750
4

103,000

<ROW RUL="s,&qdrt;">101.9(g) (9 and 101.36(f) (2)

12

1

12

4

48

<ROW RUL="s,&qdrt;">101.9(j) (18) and 101.36(h) (2) Form FDA 3570

10,000

1

10,000

8

80,000

<ROW RUL="s,&qdrt;">101.10

300,000

1.5

450,000

0.25

112,500

<ROW RUL="s,&qdrt;">101.12 (b)

29

2.3

67

1

67

<ROW RUL="s,&qdrt;">101.12 (e)

25

1

25

1

25

<ROW RUL="s,&qdrt;">101.12 (g)

5,000

1

5,000

1

5,000

<ROW RUL="s,&qdrt;">101.12 (h)

5

1

5

80

400

<ROW RUL="s,&qdrt;">101.13 (d) (1) and 101.67

200

1

200

1

200

<ROW RUL="s,&qdrt;">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

<ROW RUL="s,&qdrt;">101.13 (q) (5)

300,000

1.5

450,000

0.75

337,500

<ROW RUL="s,&qdrt;">101.14 (d) (2)

300,000

1.5

450,000

0.75

337,500

<ROW RUL="s,&qdrt;">101.15

160

10

1,600

8

12,800

<ROW RUL="s,&qdrt;">101.22 (i) (4)

25

1

25

1

25

<ROW RUL="s,&qdrt;">101.30 and 102.33

1,500

5

7,500

1

7,500

<ROW RUL="s, &qdrt;">101.36

300

40

12,000

4

48,000

<ROW RUL="s, &qdrt;">101.42 and 101.45

1,000

1

1,000

0.5

500

<ROW RUL="s, &qdrt;">101.45 (c)

5

4

20

4

80

<ROW RUL="s, &qdrt;">101.69

3

1

3

25

75

<ROW RUL="s, &qdrt;">101.70

5

1

5

80

400

<ROW RUL="s, &qdrt;">101.79 (c) (2) (i) (D)

1,000

1

1,000

0.25

250

<ROW RUL="s, &qdrt;">101.79 (c) (2) (iv)

100

1

100

0.25

25

<ROW RUL="s, &qdrt;">101.100 (d)
1,000
1
1,000
1
1,000

<ROW RUL="s, &qdrt;">101.105 and 101.100 (h)
25,000
1.03
25,750
0.5
12,875

<ROW RUL="s, &qdrt;">101.108
1
1
1
40
40

Total
1,109,873

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

<GPOTABLE COLS="6" OPTS="L2,nj,i1" CDEF="x140,16,16,16,16,16">

Table 2. Estimated Annual Recordkeeping Burden¹

21 CFR Section

No. of Record-keepers

Annual Frequency per Recordkeeping

Total Annual Records

Hours per Record

Total Hours

<ROW RUL="s, &qdrt;">101.12 (e)
25
1
25
1
25

<ROW RUL="s, &qdrt;">101.13 (q) (5)
300,000
1.5
450,000
0.75
337,500

<ROW RUL="s, &qdrt;">101.14 (d) (2)
300,000
1.5
450,000
0.75
337,500

<ROW RUL="s, &qdrt;">101.22 (i) (4)
25
1
25
1
25

<ROW RUL="s, &qdrt;">101.100 (d) (2)
1,000
1
1,000
1
1,000

<ROW RUL="s, &qdrt;">101.105 (t)
100
1
100
1
100

Total
676,150

1There 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.

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 information that is disclosed to third parties as a usual and customary part of a food producer's normal business activities. Under 5 CFR 1320.3(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.

In this request for extension of OMB approval under the PRA, FDA is no longer combining the burden hours associated with OMB Control Numbers 09100395 (collection titled, Food Labeling: Nutrition Labeling of Dietary Supplements on a 'Per Day' Basis) and 09100515 (collection titled, Food Labeling: Trans Fatty Acids in Nutrition Labeling), with the burden hours approved under OMB Control Number 09100381 (collection titled, Food Labeling Regulations) as announced previously. Such consolidation may occur in the future.

Dated: July 9, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 10????? Filed ?????10; 8:45 am]BILLING CODE 416001S

[FR Doc. 2010-17229 Filed 07/14/2010 at 8:45 am; Publication Date: 07/15/2010]