



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1155]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection activity associated with our food labeling regulations.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF

PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2013-N-1155 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling Regulations." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public docket, see 80 FR 56469,

September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility;

(2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Food Labeling Regulations--21 CFR Parts 101, 102, 104, and 105

OMB Control Number 0910-0381--Revision

This information collection supports our food labeling regulations and associated Agency guidance. Under the authority of sections 4, 5, and 6 of the Fair Packaging and Labeling Act (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 (FD&C Act) (21 U.S.C. 321, 331, 342, 343, 348, 350, 371, and 379e), we have issued regulations regarding the labeling of food. The regulations are codified in parts 101, 102, 104, and 105 (21 CFR parts 101, 102, 104, and 105) and implement statutory provisions 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. While part 101 sets forth general food labeling provisions, requirements pertaining to the common or usual name for nonstandardized foods; guidelines for nutritional quality to prescribe the minimum level or range of nutrient composition appropriate for a given class of food; and requirements for foods for special dietary use are found in parts 102, 104, and 105, respectively.

The disclosure requirements, along with the reporting and recordkeeping provisions, are necessary to ensure the safety of food products produced or sold in the United States and enable 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 consumers 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.

Specifically, the regulations set forth the general content and format requirements for food packaging, including nutrition and ingredient information. Additional regulations provide for nutrient content claims. To assist respondents in this regard, we developed the guidance document entitled "Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body." The guidance document is available from our website at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-notification-health-claim-or-nutrient-content-claim-based-authoritative-statement>. The guidance document communicates our recommendations regarding food labeling claims associated with regulations found in §§ 101.13, 101.14, 101.54, 101.69, and 101.70 (21 CFR 101.13, 101.14, 101.54, 101.69, and 101.70). It was developed to assist respondents in satisfying criteria found or discussed in these regulations regarding the submission of notifications for certain health claims and identifies information to include and information we will evaluate in determining compliance with statutory requirements (e.g., supporting literature; discussion of analytical methodology or methodologies used in support of a particular claim).

The regulations also include provisions applicable to the labeling of dietary supplements. To assist respondents in this regard and in understanding provisions under the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Pub. L. 109-462, 120 Stat. 3469), we developed the guidance document entitled "Questions and Answers: Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act." The guidance document is available from our website at: www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-labeling-dietary-supplements-required-dietary. The guidance document communicates the following information:

(1) what "domestic address" means for purposes of the dietary supplement labeling requirements in section 403(y) of the FD&C Act;

(2) FDA's recommendation for the use of an introductory statement before the domestic address or phone number that is required to appear on the product label under section 403(y); and

(3) when FDA intends to begin enforcing the labeling requirements of section 403(y).

The guidance document entitled "Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act" has also been developed to assist respondents to the information collection. The guidance document is available from our website at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-substantiation-dietary-supplement-claims-made-under-section-403r-6-federal-food>. The guidance document discusses the requirement that a manufacturer of a dietary supplement making a nutritional deficiency, structure/function, or general well-being claim have substantiation that the claim is truthful and not misleading. The guidance document

is intended to describe the amount, type, and quality of evidence FDA recommends that a manufacturer have to substantiate a claim under section 403(r)(6) of the FD&C Act.

Finally, we are revising the information collection by consolidating elements associated with revised Nutrition Facts and Supplement Facts labels regulations. Requirements included among the food labeling regulations found in part 101 govern both format and content of the Nutrition Facts (§ 101.9 (21 CFR 101.9)) and Supplement Facts (§ 101.36 (21 CFR 101.36)) labels. Currently, the information collection provisions are approved under OMB control number 0910-0813 and were established upon the implementation of associated rulemaking (RIN 0910-AF22). Now that the rulemaking is concluded, we are consolidating information collection associated with the specific regulations into this information collection.

Description of Respondents: Respondents to this information collection are manufacturers, packers, and distributors of food products, as well as certain food retailers, such as supermarkets and restaurants.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

| 21 CFR Section; Activity | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|--|--------------------|---------------------------------|------------------------|-----------------------------|-------------|
| 101.9(c)(6)(i); dietary fiber | 28 | 1 | 28 | 1 | 28 |
| 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 referenced amounts customarily consumed (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 | 1 | 1 | 1 | 40 | 40 |

| | | | | | |
|-------------|--|--|--------|--|--------|
| experiments | | | | | |
| Total | | | 10,042 | | 80,943 |

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

Table 2.--Estimated Annual Recordkeeping Burden¹

| 21 CFR Section; Activity | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
|---|----------------------|---------------------------------|----------------------|----------------------------------|-------------|
| 101.9(c)(6)(iii) ² ; added Sugars | 31,283 | 1 | 31,283 | 1 | 31,283 |
| 101.9(c)(6)(i) ² ; dietary fiber | 31,283 | 1 | 31,283 | 1 | 31,283 |
| 101.9(c)(6)(i)(A) ² ; soluble fiber | 31,283 | 1 | 31,283 | 1 | 31,283 |
| 101.9(c)(6)(i)(B) ² ; insoluble fiber | 31,283 | 1 | 31,283 | 1 | 31,283 |
| 101.9(c)(8) ³ ; vitamin E | 31,283 | 1 | 31,283 | 1 | 31,283 |
| 101.9(c)(8) ³ ; folate/folic acid | 31,283 | 1 | 31,283 | 1 | 31,283 |
| New Products | 216 | 1 | 216 | 1 | 216 |
| 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 |
| 101.7(t); recordkeeping pertaining to disclosure requirements for food not accurately labeled for | 100 | 1 | 100 | 1 | 100 |

| | | | | | |
|---------------------|--|--|-----------|--|---------|
| quality of contents | | | | | |
| Total | | | 1,089,064 | | 864,064 |

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

²These estimates are likely to be large overestimates, as not all manufacturers will need to keep records for added sugars, dietary fiber, and soluble and insoluble fiber. Manufacturers will only need to keep records for products with both added and naturally occurring sugars, added sugars that undergo fermentation in certain fermented foods, and products with non-digestible carbohydrates (soluble or insoluble) that do and do not meet the definition of dietary fiber.

³These estimates are likely to be large overestimates, as not all manufacturers will need to keep records for vitamin E and folate/folic acid. The declaration of vitamin E and folate/folic acid is not mandatory unless a health or nutrient content claim is being made or these nutrients are directly added to the food for enrichment purposes.

Table 3.--Estimated Annual Third-Party Disclosure Burden¹

| 21 CFR Section; Activity | No. of Respondents | No. of Disclosures per Respondent | Total Annual Disclosures | Average Burden per Disclosure | Total Hours |
|--|--------------------|-----------------------------------|--------------------------|-------------------------------|-------------|
| 101.3, 101.22, parts 102 and 104; statement of identity labeling requirements | 25,000 | 1.03 | 25,750 | 0.5 | 12,875 |
| 101.4, 101.22, 101.100, parts 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 part 104; labeling requirements for disclosure of nutrition information | 25,000 | 1.03 | 25,750 | 4 | 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) and (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 |
| 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 |
| Nutritional labeling for new products | 500 | 1 | 500 | 2 | 1,000 |
| Total | | | 1,513,799 | | 1,030,258 |

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

Because of the consolidation of OMB control number 0910-0813, our estimate reflects an annual increase of 188,442 responses and 188,282 hours. These estimates are based on our experience with food labeling, related submissions of petitions, and informal communications with industry.

Dated: January 29, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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