Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Section 203 of Section II: Adoption Opportunities of the Child Abuse Prevention and Treatment Act (CAPTA) (42 U.S.C. 5113).

Molly B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–10906 Filed 5–19–20; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1155]

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: Submit written comments (including recommendations) on the collection of information by June 19, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. All comments should be identified with the OMB control number 0910–0381. Also include the FDA docket number found in brackets in the heading of this document.

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, *PRAStaff@fda.hhs.gov*.

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

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 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 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 communicates our recommendations regarding food labeling claims associated with regulations found in §§ 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), we developed the guidance entitled ''Questions and Answers: Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.'' The guidance is available from our website at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-labeling-dietary-supplements-required-dietary*. The guidance 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 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 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 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 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) and Supplement Facts (§ 101.36) labels. Currently, the information collection associated with food labeling under §§ 101.9 (including petitions filed under 101.9(c)) and 101.36 (disclosures associated with serving size) is approved under OMB control number 0910–0813. These provisions were established by rulemaking (RIN 0910–AF22) and have now been incorporated into the regulations in part 101.

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.

In the **Federal Register** of February 5, 2020 (85 FR 6551), we published a notice inviting public comment on the proposed collection of information. One comment was received suggesting FDA consider including labeling requirements pertaining to folic acid, while a second comment was received that was not responsive to the information collection topics solicited. Neither comment suggested we revise our burden estimates, which are as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number 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 experiments	1	1	1	40	40
Total	.....	.....	10,042	.....	80,943

[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; activity	Number of record-keepers	Number of records per record-keeper	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 (45 minutes)	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 (45 minutes)	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)–(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 quality of contents.	100	1	100	1	100
Total	.....	.....	1,089,064	.....	864,064

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

[2] These 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.

[3] These 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 BURDEN [1]

21 CFR section; activity	Number of respondents	Number 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 (30 minutes)	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 (15 minutes)	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 (15 minutes)	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 (45 minutes)	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 (45 minutes)	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 (30 minutes)	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 (15 minutes)	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 (15 minutes)	25
101.100(d); disclosure of agreements that form the basis for exemption from the labeling requirements of section 403(c), (e), (g)–(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 (30 minutes)	12,875
Nutritional labeling for new products	500	1	500	2	1,000
Total			1,513,799		1,030,258

[1] There 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: May 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10824 Filed 5–19–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0118]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prior Notice of Imported Food

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: Submit written comments (including recommendations) on the collection of information by June 19, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0520. Also include the FDA docket number found in brackets in the heading of this document.

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, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA