The burden attributed to recordkeeping activities is assumed to be distributed among the individual elements and averaged among respondents. In the burden estimate, we assume an average burden per record of 10 hours for the RDRC respondents to maintain meeting minutes and 0.75 hours (45 minutes) for a subset of the respondents (37 RDRCs) to obtain consent of human research subjects.

Section 361.1(f) sets forth labeling requirements for radioactive drugs. These requirements are not in the burden estimate because they are information supplied by the Federal Government to the recipient for the purposes of disclosure to the public (5 CFR 1320.3(c)(2)).

Our estimated burden for the information collection reflects an overall decrease of 703 hours and a corresponding decrease of 158 responses. We attribute this adjustment to a decrease in the average burden per response, from 3.5 hours to 3 hours per response, associated with the public reporting burden for Form FDA 2915. The decrease is based on our program experience and matches the burden hours reflected on the form. In addition, this adjustment is also attributable to the Agency receiving fewer submissions over the last few years.

Dated: August 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–17154 Filed 8–9–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0918]

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

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 September 11, 2023.

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 0910–0381. 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, 10 a.m.–12 p.m., 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 Requirements

OMB Control Number 0910–0381—Revision

This information collection supports statutory and regulatory requirements that govern food labeling, and information collection recommendations discussed in associated Agency guidance. 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), establish provisions under which 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. Implementing regulations are codified in parts 101, 102, 104, and 105 (21 CFR parts 101, 102, 104, and 105). While regulations in part 101 set 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 requirements are intended 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 and include corresponding information disclosure requirements, along with the reporting and recordkeeping provisions, subject to enforcement by FDA.

We provide information resources regarding food labeling under the FD&C Act and its amendments on our website at *https://www.fda.gov/food/food-labeling-nutrition.* Food labeling is required for most prepared foods, such as breads, cereals, canned and frozen foods, snacks, desserts, drinks, etc. Nutrition labeling for raw produce (fruits and vegetables) and fish is voluntary. We refer to these products as ''conventional'' foods. For detailed information on dietary supplement labeling requirements visit our website at *https://www.fda.gov/food/dietary-supplements.* 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. Requirements include general content and format for the labeling of food packaging, including nutrition and ingredient information. Additional regulations provide for specific nutrient content claims.

The information collection includes Form FDA 3570 entitled, ''Small Business Nutrition Labeling Exemption Notice,'' for use as applicable and available for download from our website at *https://www.fda.gov/food/labeling-nutrition-guidance-documents-regulatory-information/small-business-nutrition-labeling-exemption-notice-model-form.* We have also developed the following guidance documents to assist respondents with various aspects of the information collection:

- ''*Guidance for Industry:* Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body'' (June 1998). 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

discusses section 403(r)(2) and (r)(3) (21 U.S.C. 343(r)(2) and (3)) of the FD&C Act and was issued to provide instruction on the submission of information to FDA during the initial phase of implementing these new provisions.

- ''*Questions and Answers:* Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act'' (September 2009). The guidance document 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 document communicates content elements and FDA enforcement of labeling requirements in section 403(y) of the FD&C Act.
- ''Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act'' (January 2009). 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 FDA recommendations regarding claims under section 403(r)(6) of the FD&C Act.

For operational efficiency, we are revising the information collection to account for burden that may result from activities associated with the labeling of certain beers, currently approved in OMB Control No. 0910–0728. The Tobacco Tax and Trade Bureau is responsible for the dissemination and enforcement of regulations with respect to the labeling of distilled spirits, certain wines, and malt beverages issued in the Federal Alcohol Administration Act. However, and as discussed in the guidance document ''Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration'' (December 2014), certain bottled or otherwise packaged beers are subject to section 403 of the FD&C Act. The guidance document is available for download from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-labeling-certain-beers-subject-labeling-jurisdiction-food-and-drug-administration* and provides recommendations regarding applicable labeling requirements for products under FDA's jurisdiction.

We are also revising the information collection to include new requirements applicable to the gluten-free labeling of fermented or hydrolyzed foods established through rulemaking (RIN 0910–AH00) and approved in OMB Control No. 0910–0817.

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, subject to statutory and regulatory food labeling requirements.

In the **Federal Register** of April 12, 2023 (88 FR 22045), we published a 60-day notice soliciting comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information 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)	1	1	1	80	80
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			10,038		80,623

[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 recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
101.9(c)(6)(iii); added sugars [2]	31,283	1	31,283	1	31,283
101.9(c)(6)(i); dietary fiber [2]	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); insoluble fiber [2]	31,283	1	31,283	1	31,283
101.9(c)(8); vitamin E [3]	31,283	1	31,283	1	31,283
101.9(c)(8); folate/folic acid [3]	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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
101.91; Documentation necessary to verify compliance with gluten free labeling.	5,000	56	280,000	0.45 (~27 minutes)	126,000
Total	.....	.....	1,369,064	.....	990,064

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

Our estimate reflects the cumulative average burden we attribute to the reporting and recordkeeping requirements found in the applicable regulations; individual collection activities may not be evenly distributed among respondents and/or the corresponding requirements.

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), (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 (30 minutes)	12,875
Nutritional labeling for new products	500	1	500	2	1,000
''Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration''.	12	1	12	1	12
Total	.....	.....	.....	.....	1,030,270

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

These estimates reflect our continued experience with the information collection. We have made nominal adjustments to reflect the addition of burden associated with gluten and certain bottled or otherwise packaged beer; petition submissions received since our last evaluation of the information collection; and informal communications with industry regarding food product labeling.

Dated: August 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–17145 Filed 8–9–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2986]

Agency Information Collection Activities; Proposed Collection; Comment Request; Color Additive Certification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) 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 the information collection provisions of FDA's regulations governing batch certification of color additives manufactured for use in foods, drugs, cosmetics, or medical devices in the United States.

DATES: Either electronic or written comments on the collection of information must be submitted by October 10, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 10, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2023–N–2986 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Color Additive Certification.'' 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, 240–402–7500.

- 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 dockets, 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@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