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 April 6, 2020.

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 April 6, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 6, 2020. 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 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.

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: 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 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 recordkeepers	Number 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 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	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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
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

[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: January 29, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–02253 Filed 2–4–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1427]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing and Importing of Juice

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 March 6, 2020.

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: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0466. 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.

Hazard Analysis and Critical Control Point (HACCP) Procedures for the Safe and Sanitary Processing and Importing of Juice—21 CFR Part 120

OMB Control Number 0910–0466—Extension

FDA's regulations in part 120 (21 CFR part 120) mandate the application of HACCP procedures to the processing of fruit and vegetable juices. HACCP is a preventative system of hazard control designed to help ensure the safety of foods. The regulations were issued under FDA's statutory authority to regulate food safety under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(a)(4)). Under section 402(a)(4) of the FD&C Act, a food is adulterated if it is prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. The Agency also has authority under section 361 of the Public Health Service Act (42 U.S.C. 264) to issue and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from one State, territory, or possession to another, or from outside the United States into this country. Under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act.

Under HACCP, processors of fruit and vegetable juices establish and follow a preplanned sequence of operations and observations (the HACCP plan) designed to avoid or eliminate one or more specific food hazards, and thereby ensure that their products are safe, wholesome, and not adulterated, in compliance with section 402 of the FD&C Act. Information development and recordkeeping are essential parts of any HACCP system. The information collection requirements are narrowly tailored to focus on the development of appropriate controls and document those aspects of processing that are critical to food safety.

In the **Federal Register** of September 26, 2019 (84 FR 50852), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received in response to the notice.

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

21 CFR Section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
120.6(c) and 120.12(a)(1) and (b); require written monitoring and correction records for sanitation standard operating procedures.	1,875	365	684,375	0.1 (6 minutes)	68,438
120.7; 120.10(a); and 120.12(a)(2), (b) and (c); require written hazard analysis of food hazards.	2,300	1.1	2,530	20	50,600
120.8(b)(7) and 120.12(a)(4)(i) and (b); require a recordkeeping system that documents monitoring of the critical control points and other measurements as prescribed in the HACCP plan.	1,450	14,600	21,170,000	0.01 (1 minute)	211,700
120.10(c) and 120.12(a)(4)(ii) and (b); require that all corrective actions taken in response to a deviation from a critical limit be documented.	1,840	12	22,080	0.1 (6 minutes)	2,208
120.11(a)(1)(iv) and (a)(2) and 120.12 (a)(5) and (b); require records showing that process monitoring instruments are properly calibrated and that end-product or in-process testing is performed in accordance with written procedures.	1,840	52	95,680	0.1 (6 minutes)	9,568