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: Notification Procedures for Statements on Dietary Supplements—21 CFR 101.93

OMB Control Number 0910–0331—Extension

Section 403(r)(6) of the FD&C Act (21 U.S.C. 343(r)(6)) and § 101.93 (21 CFR 101.93) require that, no later than 30 days after the first marketing, we be notified by the manufacturer, packer, or distributor of a dietary supplement that it is marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in section 403(r)(6) of the FD&C Act. In accordance with these requirements, submissions must include: (1) the name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) the signature of a responsible individual or the person who can certify the accuracy of the information presented, and who must certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

Our electronic form (Form FDA 3955) allows respondents to the information collection to electronically submit notifications to FDA via the Food Applications Regulatory Management (FARM) system. Firms that prefer to submit a paper notification in a format of their own choosing still have the option to do so; however, Form FDA 3955 prompts respondents to include certain elements in their structure/function claim notification (SFCN) described in § 101.93 in a standard electronic format and helps respondents organize their SFCN to include only the information needed for our review of the claim. Note that the SFCN, whether electronic or paper, is used for all claims made pursuant to section 403(r)(6) of the FD&C Act, including nutrient deficiency claims and general well-being claims in addition to structure/function claims. The electronic form, and any optional elements prepared as attachments to the form (*e.g.,* label), can be submitted in electronic format via FARM. Submissions of SFCNs will continue to be allowed in paper format. We use this information to evaluate whether statements made for dietary ingredients or dietary supplements are permissible under section 403(r)(6) of the FD&C Act. We also provide information on our website at *https://www.fda.gov/food/information-industry-dietary-supplements/notifications-structurefunction-and-related-claims-dietary-supplement-labeling,* which may serve as a helpful resource to respondents.

Description of Respondents: Respondents to this collection of information include manufacturers, packers, or distributors of dietary supplements that bear section 403(r)(6) of the FD&C Act statements on their labels or labeling.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity; form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
101.93; Statements for Dietary Supplements; Form FDA 3955.	3,690	1	3,690	0.75 (45 minutes) ..	2,768

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. This estimate is based on our experience with this information collection and the number of notifications received in the past 3 years, which has remained constant.

Dated: December 12, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–30231 Filed 12–18–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3379]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Laboratory Accreditation for Analyses of Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 January 21, 2025.

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 0910–0898. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Laboratory Accreditation for Analysis of Foods

OMB Control Number 0910–0898—Extension

This information collection helps to support implementation of FDA's statutory and regulatory authority governing our laboratory accreditation for analysis of foods program under section 422 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350k) and 21 CFR part 1, subpart R. FDA has statutory authority to establish a program for the testing of food by accredited laboratories; to establish a publicly available registry of recognized accreditation bodies and laboratories recognized by an accreditation body; and to require reports of any changes that would affect the recognition of such accreditation body or the accreditation of such laboratory.

The regulations require respondents to maintain and electronically submit certain test results, reports, notifications, and other records to FDA. We are clarifying that the information collection includes the use of an electronic information collection system (the FURLS Laboratory Accreditation for Analyses of Foods Program portal) (FDA Industry Systems). User guides for the Accreditation Bodies and Accredited Laboratories can be found at the following links: *https://www.fda.gov/media/156097/download?attachment* and *https://www.fda.gov/media/161685/download?attachment.* The laboratory accreditation program helps fulfill FDA's mandate to ensure the safety of the U.S. food supply and protect U.S. consumers by administering appropriate oversight of certain food testing that is of importance to public health. It also helps ensure that the testing is done in accordance with appropriate model standards, which will help produce consistently reliable and valid test results. You may access additional information about the laboratory accreditation program at: *https://www.fda.gov/food/food-safety-modernization-act-fsma/fda-recognized-accreditation-bodies-laboratory-accreditation-analyses-foods-laaf-program.* The public registry is available at *https://datadashboard.fda.gov/ora/fd/laaf.htm.*

Respondents to the information collection are accreditation bodies seeking recognition from FDA, recognized accreditation bodies, laboratories seeking accreditation from recognized accreditation bodies, and accredited laboratories. Participation in this program is voluntary for laboratories and accreditation bodies; however, only recognized accreditation bodies would be able to accredit laboratories to conduct food testing as specified in the regulations.

In the **Federal Register** of August 15, 2024 (89 FR 66417), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1] [2]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§§ 1.1113 and 1.1114; Accreditation bodies (ABs) application for recognition (one-time submission).	8	44	352	2.2068 (2 hours and 12 minutes).	776.8
§§ 1.1113 and 1.1114; ABs—application for renewal of recognition.					
§ 1.1123; ABs—reports, notifications, and documentation requirements.					
§ 1.1116(a) and (b); ABs—notices of intent to relinquish, records custodian.	1	3	3	3	9
§§ 1.1138 and 1.1139; laboratories—submission of application for LAAF-accreditation (one-time submission).	160	63.5	10,160	1.8051 (1 hour and 49 minutes).	18,340
§§ 1.1149(a) and 1.1152(c)(1), (2); laboratories—submission of sampling plan, sample collection report, and sampler qualifications.					
§§ 1.1152(d) and 1.1153(a); laboratories—qualification to submit abridged analytical reports (one-time submission).					
§ 1.1153; laboratories—abridged analytical reports submissions.					
§ 1.1149(c); laboratories—advance notice of sampling submissions.					
§ 1.1152(f); laboratories—immediate notification.					
§ 1.1140(a); laboratories—notices of intent to relinquish, records custodian.	2	3	6	1	6
§ 1.1152(c)(4) and (5); laboratories—validation and verification studies submissions.	50	5	250	1.5 (1 hour and 30 minutes).	375
§§ 1.1142; 1.1171; 1.1173; and 1.1174; requests in response to FDA action.	1	1	1	1	1
Total			10,772		19,508

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

[2] Totals may not sum due to rounding.

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

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
§ 1.1113; recordkeeping associated with ISO/IEC 17011:2017.	8	2	8	22	176
§ 1.1124; ABs—additional recordkeeping requirements a recognized accreditation body must maintain, for 5 years after the date of creation of the records, records created while it is recognized demonstrating its compliance with this subpart.					
§ 1.1138; laboratories—becoming accredited to ISO/IEC 17025:2017 (one-time); Laboratories adding ISO 17025 to become LAAF-accredited.	9	1	9	91.06 (91 hours and 4 minutes).	820
§ 1.1138; laboratories—maintaining ISO/IEC 17025: 2017 accreditation.	160	2	320	450.765 (450 hours and 46 minutes).	144,245
§ 1.1154; laboratories—additional recordkeeping requirements; a LAAF-accredited laboratory must maintain, for 5 years after the date of creation, records created and received while it is LAAF-accredited that relate to compliance with this subpart.					
Total			345		145,241

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals may not sum due to rounding.

The burden we attribute to reporting and recordkeeping activities is assumed to be distributed among the individual elements of the respective information collection activities. Although we have not received a notice of intent to relinquish records since the last approval of this information collection, we include one response for the purpose of estimating burden.

We calculate the number of food testing laboratories seeking accreditation based on the number of applicants. As a result, the number of respondents to the information collection decreased (from 170 respondents in the currently approved collection to 160 respondents). Consequently, we have adjusted our burden estimate, which results in a decrease of 227 responses and 9,303 burden hours from the currently approved information collection.

Dated: December 11, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–30230 Filed 12–18–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5581]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Additives Intended for Use in Animal Food, Food Additive Petitions, Investigational Food Additive Files Exemptions, and Declaration on Animal Food Labels

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, 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 associated with food additives intended for use in animal food, food additive petitions, investigational food additive files exemptions, and declaration of color additives on animal food labels.

DATES: Either electronic or written comments on the collection of information must be submitted by February 18, 2025.

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 February 18, 2025. 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