[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

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–2024–N–5581 for ''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.'' 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: 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 Additives Intended For Use in Animal Food, Food Additive Petitions, Investigational Food Additive Files Exemptions, and Declarations on Animal Food Labels

OMB Control Number 0910–0546—Revision

This information collection helps support implementation of FDA's authority over food additives intended for use in animal food. Misbranded foods are prohibited under section 403 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343); food additives are covered in section 409 of the FD&C Act (21 U.S.C. 348), which provides, at section 409(a) of the FD&C Act, that a food additive shall be deemed to be unsafe unless its use is permitted by a regulation that prescribes the condition(s) under which it may safely be used, or unless it is exempted by regulation for investigational use. Section 409(b) of the FD&C Act provides for petitions to establish safety of food additives and specifies information that must be submitted to FDA before a regulation permitting its use may be issued. Agency regulation in 21 CFR part 570 sets forth general provisions applicable to food additives intended for use in animal food; provides relevant definitions; establishes principles for determining safety; and explains prescribed elements to be included in a Generally Recognized as Safe (GRAS) notice. The regulation also provides for certain exemptions for investigational use and discusses related procedures. Agency regulation in 21 CFR part 571 establishes procedural requirements applicable to the submission of petitions filed under section 409(b) of the FD&C Act, including content and format elements to facilitate FDA processing of a food additive petition. Finally, Agency regulation in 21 CFR part 501 establishes disclosure requirements for animal food labeling, including the disclosure of the presence of certified and noncertified color additives (21 CFR 501.22(k)). Additional disclosure requirements are found in 21 CFR parts 573 (food additives permitted in feed and drinking water of animals) and 579 (irradiation in the production, processing, and handling of animal food), and are included in the scope of coverage for the information collection.

We are revising the information collection to include related authority established through enactment of the Animal Drug and Animal Generic Drug

User Fee Amendments of 2018 (2018 Amendments) (Pub. L. 115–234). Intending to help ensure the safety of pet food, section 306(c) of the 2018 Amendments provides for the issuance of guidance on pre-petition consultations for animal food additives. We have issued the following guidance documents to assist respondents in this regard:

Guidance for Industry (GFI) #262, ''Pre-Submission Consultation Process for Animal Food Additive Petitions or Generally Recognized as Safe (GRAS) Notices'' (December 2020), available for download from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-262-pre-submission-consultation-process-animal-food-additive-petitions-or-generally.* The guidance document describes the types of information our Center for Veterinary Medicine recommends be included in:

1. pre-petition consultations prior to submission of food additive petitions (FAP) for food additives intended for use in animal food;

2. pre-submission consultations regarding an animal food substance for which an entity plans to provide notice of its conclusion that the intended use of the substance is GRAS under FDA's animal food GRAS Notification program; or

3. a Food Use Authorization request to permit the use, in human or animal foods, of animal products derived from animals that have been administered an investigational substance intended for use in animal food.

Additionally, GFI #294, ''Animal Food Ingredient Consultation (AFIC)'' (August 2024), available for download at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-294-animal-food-ingredient-consultation-afic,* describes the AFIC process, which provides for a way, within the regulatory framework, for firms that are developing animal food ingredients to consult with FDA, and for FDA to review information from developers and the public regarding the ingredients and any relevant safety concerns. The AFIC process includes opportunities for public awareness of, and input on, the ingredients for which FDA is providing consultation. The guidance document also explains that FDA generally would not intend to take enforcement action against an ingredient for being an unapproved animal food additive if FDA has sent an AFIC ''consultation complete'' letter, provided the ingredient is used in accordance with the terms described in the letter and there continues to be no questions or concerns about the safety of the ingredient.

Description of Respondents: Respondents to this collection of information are animal food manufacturers or animal food additive manufactures. With regard to submission activities, we assume 2,508 respondents based on the number of registrants who identify as animal food additive manufacturers. With regard to labeling activities under 21 CFR 501.22(k), we assume 3,120 respondents based on information found in previous Agency rulemaking (RIN–0910AG02) regarding declarations for animal food product labels.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Regulatory authority; submission of information	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Food Additive Petitions					
21 CFR 571.1(c) Moderate Category	3	1	3	3,000	9,000
21 CFR 571.1(c) Complex Category	3	1	3	10,000	30,000
21 CFR 571.6 Amendment of Petition	5	1	5	1,300	6,500
Investigational Food Additive Files					
21 CFR 570.17 Moderate Category	8	1	8	1,500	12,000
21 CFR 570.17 Complex Category	10	1	10	5,000	50,000
Animal Food Ingredient Consultation					
Consultation Category	12	1	12	3,000	36,000
Amendment of Consultation	12	1	12	1,300	15,600
Color Additives					
21 CFR 501.22(k); labeling of color additive or lake of color additive; labeling of color additives not subject to certification.	3,120	0.8292	2,587	0.25 (15 minutes)	647
Total Hours					159,747

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

We have determined that food additive petitions and investigational food additive files that are submitted, fall into one of two categories of complexity. Fluctuations in the number and types of food and color additive petitions received in any given year are governed by market forces.

§ 571.1(c) Moderate Category: For a food additive petition without complex chemistry, manufacturing, efficacy and/or safety issues, the estimated time requirement per petition is approximately 3,000 hours. We estimate that, annually, 3 respondents will submit 1 such petition, for a total of 9,000 hours.

§ 571.1(c) Complex Category: For a food additive petition with complex chemistry, manufacturing, efficacy and/or safety issues, the estimated time requirement per petition is approximately 10,000 hours. We estimate that, annually, 3 respondents will each submit 1 such petition, for a total of 30,000 hours.

§ 571.6 Amendment of Petition: For a food additive petition amendment, the estimated time requirement per petition is approximately 1,300 hours. We estimate that, annually, 5 respondents will each submit 1 such amendment, for a total of 6,500 hours.

§ 570.17 Moderate Category: For an investigational food additive file without complex chemistry, manufacturing, efficacy and/or safety issues, the estimated time requirement per file is approximately 1,500 hours. We estimate that, annually, 8 respondents will each submit 1 such file, for a total of 12,000 hours.

§ 570.17 Complex Category: For an investigational food additive file with complex chemistry, manufacturing, efficacy and/or safety issues, the estimated time requirement per file is approximately 5,000 hours. We estimate that, annually, 10 respondents will each submit 1 such file, for a total of 50,000 hours.

Consultation Category: We estimate developers of animal food ingredients will spend 3,000 hours consulting with FDA on an ingredient. We estimate that, annually, 12 respondents will consult with FDA, for a total of 36,000 hours.

The labeling requirements for food and color additives were designed to specify the minimum information needed for labeling in order that food and color manufacturers may comply with all applicable provisions of the FD&C Act and other specific labeling acts administered by FDA. Label information does not require any additional information gathering beyond what is already required to assure conformance with all specifications and limitations in any given food or color additive regulation. Label information does not have any specific recordkeeping requirements unique to preparing the label. Therefore, because labeling requirements for a particular color additive or food additive involve information required as part of the safety review process, the burden hours for labeling are included in the estimate for 21 CFR 501.22(k) and 571.1.

We base our estimate of the total annual responses on submissions received over the last 3 years. We base our estimate of the hours per response on our experience with the labeling, food additive petition, and filing processes.

Based on review of the information collection, there was a decrease of food additive petition (FAP) responses and a corresponding decrease in burden hours for FAPs. We attribute this adjustment to an increase in the number of GRAS notices (21 CFR part 570, subpart E) received, which tend to substitute for FAP submissions due to a similar quantity and quality of data and information requirement. These numbers can fluctuate year to year. We also note that investigational food additive file responses have increased due to more respondents providing information during the pre-market process prior to providing a more formal regulatory response (*e.g.,* FAP or GRAS notice). We did not adjust the number of responses received for the declaration of color additives on animal food labels from the previous collection.

Our estimated burden for the information collection reflects an overall increase of 40,600 total hours and 24 responses. We attribute this to accounting for the consultation process for firms developing animal food ingredients.

Dated: December 12, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–30227 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–1055]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request Data To Support Social and Behavioral Research as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, us, 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 0910–0847. 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.

Data To Support Social and Behavioral Research as Used by the Food and Drug Administration

OMB Control Number 0910–0847—Extension

This information collection is intended to support FDA-conducted research. Understanding patients, consumers, and healthcare professionals' perceptions and behaviors plays an important role in improving FDA's regulatory decision-making processes and communications that affect various stakeholders. FDA uses the following methodology to achieve these goals: (1) creation and validation of survey instruments; (2) use of techniques to evaluate sampling and recruitment methods; (3) evaluation of the validity and reliability of survey instruments; (4) individual in-depth interviews, (5) general public focus group interviews, (6) intercept interviews, (7) self-administered surveys, (8) gatekeeper surveys, and (9) focus group interviews. These methods serve the narrowly defined need for direct and informal opinion on a specific topic and serve as a qualitative and quantitative research tool having two major purposes:

- Obtaining useful, valid, and reliable information for the development of variables and measures for formulating the basic objectives of social and behavioral research and
- Successfully communicating and addressing behavioral changes with intended audiences to assess the potential effectiveness of FDA communications, behavioral interventions, and other materials.

While FDA will use these methods to test and refine its ideas and help develop communication and behavioral strategies research, the Agency will generally conduct further research before making important decisions (such as adopting new policies and allocating or redirecting significant resources to support these policies).