Ave., Bldg. 71, Silver Spring, MD 20993–0002, 202–657–8533, *CBERVRBPAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. On December 12, 2024, under Topic I, the Committee will meet in open session to discuss Considerations for RSV Vaccine Safety in Pediatric Populations. Under Topic II, the Committee will meet in open session to hear overviews of the LI and LR research programs in the Division of Viral Products, Office of Vaccines Research and Review, and Center for Biologics Evaluation and Research. After the open session ends for Topic II, the meeting will be closed to the public for Committee deliberations.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at: *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: On December 12, 2024, from 8:30 a.m. to 3 p.m. Eastern Time for Topic I and from 3:10 p.m. to 4:40 p.m. Eastern Time for Topic II, the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before December 4, 2024, will be provided to the Committee. Comments received on or after December 4, 2024, and by December 11, 2024, will be taken into consideration by FDA. Oral presentations from the public will be scheduled between approximately 12:15 p.m. to 1 p.m. Eastern Time for Topic I, and between 4:25 p.m. to 4:40 p.m. Eastern Time for Topic II. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, along with their names, email addresses, and direct contact phone numbers of proposed participants, and an indication of the approximate time requested to make their presentation on or before 12 p.m. Eastern Time on November 25, 2024. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 27, 2024.

Closed Committee Deliberations: On December 12, 2024, the meeting will be closed from 4:40 p.m. to 5:30 p.m. to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The recommendations of the advisory committee regarding the progress of the individual investigators' research programs, along with other information, will be discussed during this session. We believe that public discussion of these recommendations on individual scientists would constitute an unwarranted invasion of personal privacy.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Sussan Paydar or Kathleen Hayes (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. No participant will be prejudiced by this waiver, and that the ends of justice will be served by allowing for this modification to FDA's advisory committee meeting procedures.

Dated: October 18, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–24713 Filed 10–23–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2177]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Animal 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 November 25, 2024.

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 0910–0751. 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.

Current Good Manufacturing Practice and Hazard Analysis, and Risk-Based Preventive Controls for Human Food—21 CFR part 117; Current Good Manufacturing Practice and Hazard Analysis, and Risk-Based Preventive Controls for Animal Food—21 CFR part 507

OMB Control Number 0910–0751—Extension

This information collection supports implementation of section 418 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350g). Section 418(a) requires the owner, operator, or agent in charge of a facility to evaluate hazards that could affect food manufactured, processed, packed, or held by the facility; identify and implement preventive controls; monitor the performance of those controls; and maintain records demonstrating compliance. Section 418(b) through (i) of the FD&C Act contains more specific requirements applicable to facilities, including corrective actions (section 418(e)), verification (section 418(f)), a written plan and documentation (section 418(h)), and reanalysis of hazards (section 418(i)). Finally, section 301(uu) of the FD&C Act (21 U.S.C. 331(uu)) prohibits ''[t]he operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418 [of the FD&C Act].'' FDA has issued regulations in part 117 (21 CFR part 117) governing human food, while regulations governing food for animals are found in part 507 (21 CFR part 507). The purpose of the regulations is to prevent the introduction of adulterated and/or misbranded products into the marketplace and ensure the safety of both human foods and animal foods in accordance with sections 402 and 403 of the FD&C Act (21 U.S.C. 342 and 343). Generally, domestic and foreign food facilities that are required to register in accordance with section 415 of the FD&C Act (21 U.S.C. 350d) must comply with these requirements, unless an exemption applies. It is important to note that applicability of the current good manufacturing practice requirements for animal food is dependent upon whether a facility is required to register, while the applicability of the current good manufacturing practice requirements for human food is not dependent upon whether a facility is required to register. Respondents to the information collection are those who manufacture, prepare, pack, or hold food intended for humans or animals.

The regulations include recordkeeping necessary to demonstrate compliance with the requirements; however, respondents that meet the definition of a ''qualified facility,'' under §§ 117.3 and 507.3, are subject to reporting. To be subject to the modified requirements set forth in part 117, subpart D and part 507, subpart D for human food and animal food, respectively, respondents must attest to their status. To assist respondents in this regard, we have developed Forms FDA 3942a (Quality Facility Attestation: Human Food) and 3942b (Quality Facility Attestation: Animal Food), available for downloading from our website at *https://www.fda.gov/food/registration-food-facilities-and-other-submissions/qualified-facility-attestation.*

Information collected will assist FDA in determining facility compliance with current good manufacturing practice requirements and in ensuring that food safety systems include hazard analysis and risk-based preventive controls. Records will be examined during food facility inspections and in the event of an outbreak or other food safety incident involving the food manufactured at the facility.

Section 418(l)(2)(B)(ii) of the FD&C Act directs us to issue guidance on documentation required to determine status as a qualified facility. Accordingly, we issued a guidance for industry entitled ''Determination of Status as a Qualified Facility Under Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Part 507: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals,'' also available for downloading from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-determination-status-qualified-facility.* The guidance discusses the content, format, frequency, and timing of submissions.

In the **Federal Register** of June 5, 2024 (89 FR 48172) we published a 60-day notice requesting public comment on the proposed collection of information. Although no comments were received, on our own initiative we have modified estimates since publication of our 60-day notice. Specifically, we have modified estimates for certain recordkeeping elements associated with animal foods in tables 2 and 3.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; reporting activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Human Foods: 117.201(c); qualified facility as reported on Form FDA 3942a	37,134	[2] 0.5	18,567	0.5 (30 minutes)	9,284
Animal Foods: 507.7(c); qualified facility as reported on Form FDA 3942b	1,120	0.5	560	0.5 (30 minutes)	280
Total					9,564

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section; recordkeeping activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [2]
Human Foods: Subparts A—Required Records and B—General Provisions					
117.126(c) and 117.170(d); food safety plan and reanalysis	46,685	1	46,685	110	5,135,350
117.136; assurance records	16,285	1	16,285	0.25 (15 minutes)	4,071
117.145(c); monitoring records	8,143	730	5,944,390	0.05 (3 minutes)	297,220
117.150(d); corrective actions and corrections records	16,285	2	32,570	1	32,570
117.155(b); verification records	8,143	244	1,986,892	0.05 (3 minutes)	99,345
117.160; validation records	3,677	6	22,062	0.25 (15 minutes)	5,515
117.475(c)(7) through (c)(9); supplier records	16,285	10	162,850	4	651,400
117.180(d); training records for preventive controls qualified individual	46,685	1	46,685	0.25 (15 minutes)	11,671
Subpart A—General Provisions					
507.4(d); documentation of animal food safety and hygiene training	7,469	0.75	5,579	0.05 (3 minutes)	279
Subpart C—Hazard Analysis and Risk-Based Preventive Controls					
507.31 through 507.55; food safety plan—including hazard analysis, preventive controls, and procedures for monitoring, corrective actions, verification, recall plan, validation, reanalysis, modifications, and implementation records	7,469	519	3,876,411	0.1 (6 minutes)	387,641
Subpart E—Supply Chain Program					
507.105 through 507.175; written supply-chain program—including records documenting program	7,469	519	3,876,411	0.1 (6 minutes)	387,641
Subpart F—Requirements Applying to Records That Must Be Established and Maintained					
507.200 through 507.215; general requirements, additional requirements applying to food safety plan, requirements for record retention, use of existing records, and special requirements applicable to written assurance	7,469	519	3,876,411	0.1 (6 minutes)	387,641
Total					7,400,400

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Total hours have been rounded.

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
117.201(e); disclosure of food manufacturing facility address	37,134	1	37,134	0.25 (15 minutes)	9,284
507.27(b); labeling for the animal food product contains the specific information and instructions needed so the food can be safely used for the intended animal species	330	10	3,300	0.25 (15 minutes)	825
507.7(e)(1); change labels on products with labels	1,120	4	4,480	1	4,480
507.7(e)(2); change address on labeling (sales documents) for qualified facilities	974	1	974	1	974

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
507.25(a)(2); animal food, including raw materials, other ingredients, and rework, is accurately identified	373	312	116,376	0.01 (36 seconds)	1,163.76
507.28(b); holding and distribution of human food by-products for use as animal food	40,798	2	81,596	0.25 (15 minutes)	20,399
Total					37,125.76

[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.

Dated: October 21, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–24771 Filed 10–23–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Environmental Information and Documentation

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate below or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than December 23, 2024.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: HRSA Environmental Information and Documentation, OMB No. 0915–0324—Extension.

Abstract: HRSA proposes an extension of the Paperwork Reduction Act approval for the Environmental Information and Documentation (EID) checklist, which consists of information the agency is required to obtain to comply with the National Environmental Policy Act (NEPA) of 1969 as amended by the Fiscal Responsibility Act of 2023. NEPA establishes the federal government's national policy for protection of the environment. The EID checklist must be completed and submitted by applicants for HRSA funds that plan to engage in construction or other projects that will potentially impact the environment. HRSA uses the checklist to ensure that decision-making processes are consistent with NEPA and other related environmental and historic preservation laws. The extension will support HRSA's implementation of programs with capital improvements that have the potential to significantly affect the human environment, such as construction/expansion and alteration/renovation activities, as defined in the associated HRSA program guidance, or installation of fixed equipment.

Need and Proposed Use of the Information: Applicants for HRSA funds must provide information and assurance of compliance with NEPA on the EID checklist. This information is reviewed during the Pre-Award stage (and/or prior to the implementation of the project). The information is reviewed in the Post-Award stage for project changes and the information is reviewed before the implementation of the project changes.

Likely Respondents: HRSA applicants applying for federal loan guarantees, federal construction grants, and cooperative agreements.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.