UNITED STATES FOOD & DRUG ADMINISTRATION

Current Good Manufacturing Practice (CGMP), Hazard Analysis,
and Risk-Based Preventive Controls For Human Food and Food for Animals

OMB Control No. 0910-0751 - Extension

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

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. Sections 418(b)-(i) contain 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 promulgated regulations in 21 CFR part 117 governing human food while regulations governing food for animals are found in 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 21 CFR 117.3 and 507.3 are subject to reporting, through filing an attestation. To be subject to the modified requirements set forth in part 117, subpart D and part 507, subpart A for human food and animal food, respectively, respondents must attest to their status. To assist respondents in this regard, we 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.

Section 418(l)(2)(B)(ii) of the FD&C Act (21 U.S.C. 350g(l)(2)(B)(ii)) 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,*" (Sept. 2018), 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.

We are therefore requesting approval of the information collections found in 21 CFR parts 117 and 507, Forms FDA 3942a and FDA 3942b, and the associated procedural guidance, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

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.

Description of Respondents: Respondents to the information collection are those who manufacture, prepare, pack, or hold food intended for humans or animals.

3. Use of Improved Information Technology and Burden Reduction

The information collection requirements solicit what we believe is the minimal information necessary to help ensure protection of the U.S. food supply by preventing the introduction of hazards and introducing preventative controls. Forms FDA 3942a and 3942b may be submitted electronically via the FURLS electronic portal (https://www.access.fda.gov/) or by mail, however we encourage electronic submissions. We expect respondents will implement electronic recordkeeping most compatible with current business practices. Under the regulations, records must be made available upon FDA request during an inspection or to review a food safety incident.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The information collection poses no undue burden on small entities. We aid small businesses in dealing with the requirements of the Federal Food, Drug, and Cosmetic Act through the agency's Regional Small Business Representatives and through the scientific and administrative staffs

within the agency. Additional assistance is available for small businesses via the agency's website at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements. If corrective actions are necessary, further monitoring will be conducted. Data can be collected hourly, daily, weekly, or yearly as determined by the hazards encountered in a particular manufacturing process. We believe the information collection schedule represents the least burdensome means necessary to ensure the effectiveness of the regulations and ensure food safety.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment in the *Federal Register* of June 5, 2024 (89 FR 48172). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to respondents associated with this collection of information.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related performed for their employer (e.g., point of contact at a regulated entity). PII is collected to support FDA's commitment to prevent the introduction of adulterated and/or misbranded products into the marketplace and ensure the safety of both human foods and animal food in accordance with sections 402 and 403 of the FD&C Act (21 U.S.C. 342 and 343). The PII submitted via **Form FDA 3942a** (Qualified Facility Attestation for Human Food Facility) and **Form FDA 3942b** (Qualified Facility Attestation for Animal Food Facility) is name, work address, work email address, work telephone number, and fax telephone number. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, the contractor or FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

This collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section; Reporting	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
117.201(c); qualified facility as reported on Form FDA 3942a	37,134	0.5[2]	18,567	0.5 (30 minutes)	9,284
507.7(c); qualified facility as reported on Form FDA 3942b	1,120	0.5	560	0.5 (30 minutes)	280
Total			19,127		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; Activity	No. of Recordkeepers	No. of Records Per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours[2]
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)	5,516
117.475(c)(7)-(9); supplier records	16,285	10	162,850	4	651,400
117.180(d); training	46,685	1	46,685	0.25	11,671

21 CFR Section; Activity	No. of Recordkeepers	No. of Records Per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours[2]
records for preventive controls qualified individual				(15 minutes)	
ANIMAL FOODS Subpart A--General Provisions					
507.4(d); documentation of animal food safety and hygiene training	7,469	0.75	5,602	0.05 (3 minutes)	280
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			19,893,254		7,400,346

[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	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours[2]
117.201(e); disclosure of food manufacturing facility address	37,134	1	37,134	0.25 (15 minutes)	9,284

21 CFR Section; Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours[2]
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); disclosure of manufacturing address	1,120	1	1,120	0.25 (15 minutes)	280
507.25(a)(2); animal food, including raw materials, other ingredients, and rework, is accurately identified	373	312	116,376	0.01 (36 seconds)	1,164
507.28(b); holding and distribution of human food byproducts for use as animal food	40,798	2	81,596	0.25 (15 minutes)	20,399
Total			239,526		31,952

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

12b. Annualized Cost Burden Estimate

Our estimate of the average hourly wage for qualified individuals, industrial production managers, and food manufacturing production workers that implement and maintain food safety plans and continued analysis of those plans are based on the median hourly wage rate found in the Bureau of Labor Statistics, "May 2023 National Occupational Employment and Wage Estimates," (https://www.bls.gov/oes/current/oes_nat.htm#23-0000). The median hourly wage rates have been doubled in Table 4 to account for overhead costs. The overall estimated cost incurred by respondents to review, implement, and maintain food safety plans is $957,039,305.44 ($132.16/hour x 6,237,142 hours for qualified individuals plus $112.48/hour x 1,163,204 hours for industrial production managers plus $45.80 x 41,516 hours for food manufacturing production workers).

We base our estimate for respondents costs for implementation, maintenance, and continued analysis of a food safety plan on wage data available from the Bureau of Labor Statistics.

Table 4.--Estimated Annual Cost Burden

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Qualified Individual	6,237,142	$132.16	$824,300,686.72
Industrial Production Manager	1,163,204	$112.48	$130,837,185.92
Food Manufacturing Production Worker	41,516	$45.80	$1,901,432.80
Total			044

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

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

14. Annualized Cost to the Federal Government

Management of the information collection is covered through existing resource allocations for food safety. However, we estimate an annual cost of $50,000 to the Federal government responding to inquiries specific to this collection of information based on past experiences related to this subject matter.

15. Explanation for Program Changes or Adjustments

The information collection reflects adjustment. First, with regard to human foods, we removed the individual element "*Reporting: qualified facilities*," as the attendant burden is captured in the line item "*Quality Facility Attestation*." For animal foods, we combined two individual IC elements for §§ 507.7(e)(1) and 507.7(e)(2) into one line item for 507.7(e), further decreasing the overall burden by 5,174 hours and 4,334 responses annually. We attribute the latter adjustment to animal food respondents complying with manufacturing address disclosures. We also corrected some inadvertent rounding and calculation errors. Cumulatively the adjustments result in a decrease of **23,438** responses and **14,513** hours annually to our estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Consistent with established practice FDA will publish a *Federal Register* notice announcing OMB approval of the information collection associated with this guidance document and will display in that notice both the OMB control number and its current expiration date. In addition, the OMB control number will be displayed on the guidance document cover page and include a link to www.reginfo.gov to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.