UNITED STATES FOOD & DRUG ADMINISTRATION

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

OMB Control No. 0910-0751 - Revision

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 (FFDCA)(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 (§ 418(e)), verification (§ 418(f)), a written plan and documentation (§ 418(h)), and reanalysis of hazards (§ 418(i)). Finally, section 301(uu) of the FFDCA (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. Respondents to the information collection are those who manufacture, prepare, pack, or hold food intended for humans or animals. 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 food in accordance with sections 402 and 403 of the FFDCA (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 FFDCA (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.

The regulations include recordkeeping necessary to demonstrate compliance with statutory requirements; however, respondents that meet the definition of a "*qualified facility*," under 21 CFR 117.3 and 507.3, are subject to modifications. To be subject to the modified requirements set forth in part 117, subpart D and part 507, subpart A for human food and food for animals, 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: Food for Animals*), 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 and we have

issued the guidance document 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.

We are therefore requesting OMB approval of the information collection found in 21 CFR parts 117 and 507, along with 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.

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 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. We have revised the information collection to include related activities previously approved in separate collections to improve efficiency of agency operations and management of our active inventory.

5. Impact on Small Businesses or Other Small Entities

The information collection poses no undue burden on small entities. At the same time, we provided extended and staggered compliance dates for respondents qualifying as small businesses, as well as establishing modified requirements for qualified facilities. FDA provides small business compliance guides to assist respondents with statutory and regulatory requirements.

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 believes 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 March 16, 2021 (86 FR 14436). 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

There is no assurance of confidentiality associated with this collection of information.

11. Justification for Sensitive Questions

This collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

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

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					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: Human Foods[1]

21 CFR Section; Activity	No. of Recordkeepers	No. of Records Per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
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)-(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
Total					6,237,142

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

Table 3.--Estimated Annual Recordkeeping Burden: Food for Animals[1]

21 CFR Section; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours[2]
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	7,469	519	3,876,411	0.1 (6 minutes)	387,641

21 CFR Section; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours[2]
requirements applicable to written assurance					
Total			11,635,372		1,163,258

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

Table 4.--Estimated Annual Third-Party Disclosure Burden: Human Foods[1]

21 CFR Section; Activity	No. of Respondents	No. 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

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

Table 5--Estimated Annual Third-Party Disclosure Burden: Food for Animals[1]

21 CFR Section; Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
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
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 byproducts for use as animal food	40,798	2	81,596	0.25 (15 minutes)	20,399
Total					27,841.76

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

12b. Annualized Cost Burden Estimate

We estimate respondent costs for implementation and maintenance of a food safety plan and continued analysis, and based on wage data available from government, industry, and academic sources.

Annualized Cost Burden Estimate			
Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Qualified Individual	6,237,142	$56.00	$349,279,952
Industrial Production Manager	1,163,258	$47.78	$55,580,467.24
Food Manufacturing Production Worker	9,564	$19.91	$190,419.24
Total			0

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/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 and we estimate no costs to the Federal government.

15. Explanation for Program Changes or Adjustments

The information collection reflects changes and adjustments. We have revised the information collection to include related activities associated with food for animals, currently approved under 0910-0789. This results in an increase to the collection by 11,842,098 responses and 1,191,100 burden hours annually.

16. Plans for Tabulation and Publication and Project Time Schedule

Information will not be published for statistical use.

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

FDA will display the expiration date of OMB approval as required by 5 CFR 1320.5 (and 5 CFR 1320.8(b)(1)), however because documents are more frequently being accessed electronically we are considering technological changes that will enable us to display the expiration date by linking to approval information found at www.reginfo.gov. We intend to include the OMB control number and expiration date on the guidance landing page, allowing those who download the document an easily identifiable option to view this information. This also allows the agency to more easily update the expiration date upon renewal and/or revision of OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.