United States Food and Drug Administration
Current Good Manufacturing Practice and Hazard Analysis and
Risk-Based Preventive Controls for Food for Animals

OMB Control No. 0910-0789

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

As amended by the Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA) (Pub. L. 111-353), the Federal Food, Drug, and Cosmetic Act (the FD&C Act) enables FDA to better protect the public health by helping to ensure the safety and security of the food supply. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA recognizes the important role industry plays in ensuring the safety of the food supply, including the adoption of modern systems of preventive controls in food production. Specifically, section 418 (21 U.S.C. 350g) of the FD&C Act sets forth requirements for hazard analysis and risk-based preventive controls for facilities that produce food for animals. To implement these provisions, regulations were codified under 21 CFR part 507--*Current Good Manufacturing Practice, Hazard Analysis, And Risk-Based Preventive Controls For Food For Animals.* The regulations establish requirements for a written food safety plan; hazard analysis; preventive controls; monitoring; corrective actions and corrections; verification; supply-chain program; recall plan; and associated records.

The regulations in 21 CFR part 507 require animal food facilities to establish and implement hazard analysis and risk-based preventive controls, and implement current good manufacturing practice. The regulations include requirements for animal food facilities to have a written food safety plan, including a hazard analysis; a description of preventive controls (including recall procedures) for hazards requiring a preventive control; a supply-chain program (if applicable); a description of monitoring procedures for those preventive controls; a description of corrective actions for any failure of the preventive controls; a description of verification procedures; and recordkeeping procedures. The information collection provisions are necessary to ensure the safety of animal food in response to the FSMA and FDAAA statutory mandates. The records are used by respondents and FDA to verify, for example, that hazards have been identified, appropriate control measures have been implemented and are effective, and that appropriate corrective actions were taken if the control measures were not implemented or a problem occurred.

Accordingly, we are requesting extension of OMB approval for the information collection provisions found in 21 CFR part 507 and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The required records are used by both the respondents and the FDA. The records are used to verify that appropriate control measures have been implemented and are effective, and that appropriate corrective actions were taken if the control measures were not implemented or a problem occurred. Such verification activities are essential to ensure that preventive controls are working as planned. We review the records during the conduct of periodic facility inspections. This permits us to determine whether the animal food has been consistently manufactured/processed, packed, or held in conformance with appropriate preventive controls requirements.

Description of Respondents: Respondents to this information collection are owners, operators, or agents in charge of domestic or foreign facilities that manufacture, process, pack, or hold food for animal consumption in the United States. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

The regulation does not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by facilities. Facilities are free to use whatever forms of information technology may best assist them in retaining the appropriate records and making them available to regulatory officials. We estimate that about ninety percent (90%) of respondents will keep some of the required records electronically in the next three years.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Each facility is responsible for the required labeling and recordkeeping associated with the animal food it manufactures/processes, packs, or holds. We are unaware of similar recordkeeping requirements that could substitute for those established by the applicable regulations.

5. Impact on Small Businesses or Other Small Entities

The information collection does not impose undue burden on small entities. We provided for extended and staggered compliance dates for respondents qualifying as small businesses. Similarly, "very small businesses," defined as those businesses (including subsidiaries and affiliates) averaging less than $2.5 million, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale), are not required to comply with subpart B of this rule until 2018, and are not required to submit attestations as a qualified facility until 2019.

Finally, certain other on-farm facilities that are small and very small businesses and only engage in manufacturing, processing, packing, or holding activities that have been

determined to be low-risk activity/animal food combinations, are exempt from the hazard analysis and preventive controls requirements. Also, certain animal food facilities that produce low-acid canned foods are exempt from the microbiological hazard requirements of the hazard analysis and preventive controls requirements, provided that they are in compliance with 21 CFR part 113. Along with the very small businesses, other qualified facilities are exempt from the hazard analysis and preventive controls requirements of this rule, but are subject to the requirements in subpart B (Current Good Manufacturing Practice) and related requirements in subpart A (see 21 CFR 507.4).

We aid small businesses in complying with our requirements through our Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We have provided a Small Business Guide on our website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. The information is collected consistent with the Food Safety Plan of the respondents' facilities. Data may be collected hourly, daily, weekly, or yearly as determined by each facility's Food Safety Plan. Less frequent recordkeeping would reduce or nullify the effectiveness of the regulations to provide assurance to both the facility and FDA that the animal food is safe. We do not collect records as a routine matter. Records remain on file at each facility or offsite if accessible within 24 hours. We would examine the records during a periodic inspection or during an investigation.

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

All of the reporting requirements are consistent with 5 CFR 1320.5.

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 May 24, 2018 (83 FR 24124). Although three comments were received, none were responsive to the four collection of information topics solicited and were therefore not addressed.

9. Explanation of Any Payment or Gift to Respondents

The information collection does not provide for payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

This regulation does not provide pledges of confidentiality. However, records that may be reviewed during FDA inspections are subject to FDA regulations on the release of information in 21 CFR part 20. Confidential commercial information is protected from

disclosure under FOIA in accordance with section 552(a) and (b) (5 U.S.C. 552(a) and (b)) and by part 20. To the extent that § 20.64 applies, we will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

We estimate our burden of the information collection as follows:

Table 1.--Estimated Annual Reporting Burden

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
507.7 exemption: submit attestation of preventive controls or compliance with State and local laws (non-federal)	1,120	0.5	560	0.5 (30 minutes)	280
507.67, 507.69, and 507.71; submission of an appeal, including submission of a request for an informal hearing	1	1	1	4	4
507.85(b); requests for reinstatement of exemption	1	1	1	2	2
Total					286

Table 2.--Estimated Annual Recordkeeping Burden

21 CFR Section; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Subpart A--General Provisions					
507.7(e); records attesting that the facility is a "qualified" facility	1,120	0.5	560	0.1 (6 minutes)	56
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, monitoring, corrective actions, verification,	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
validation reanalysis, modifications, and implementation records.					
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					
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
Totals			11,635,372		1,163,258

Table 3.--Estimated Annual Third-Party Disclosure Burden

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	1,526	4	6,104	1	6,104
507.7(e)(2); change address on labeling (sales documents) for qualified facilities	1,329	1	1,329	1	1,329
507.25(a)(2); animal food, including raw materials, other ingredients, and rework, is accurately identified	330	312	102,960	0.01 (36 seconds)	1,030
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					29,687

These figures are based on our regulatory impact analysis in support of the final rule for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, which published in the *Federal Register* of September 17, 2015 (80 FR 56170). Using Agency data, we estimated the number of animal food facilities that we believe are subject to the regulations. We base our estimate of the time necessary for the individual reporting, recordkeeping, and third-party disclosure activities on our experience with similar information collections.

12b. Annualized Cost Burden Estimate

"Type of Respondent"	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Clerk (4%)	46,762	$22.40	$1,047,468.80
First Line Supervisor (3%)	35,071	$31.62	$1,108,945.02
Consultant (5%)	58,452	$69.34	$4,053,061.68
Total			

[1] May 2017 National Industry-Specific Occupational Employment and Wage Estimates, US Department of Labor, Bureau of Labor Statistics (https://www.bls.gov/oes/current/naics4_311100.htm) hourly wage plus 30% adjusted for benefits.

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

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Costs to the Federal government are covered by existing resource allocations.

15. Explanation for Program Changes or Adjustments

We are retaining the currently approved burden estimate. The final rule establishing the need for the information collection became effective November 16, 2015, however compliance dates were staggered for small and very small businesses. As a result of the continued implementation of the regulatory provisions, we continue to evaluate and invite comment on the estimated burden associated with the information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Information is not to be published for statistical use.

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

Display of the OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.