Current Good Manufacturing Practice and Hazard Analysis and
Risk-Based Preventive Controls for Food for Animals
OMB Control No. 0910-0789
RIN 0910-AG10

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

This rulemaking is being issued to satisfy the requirements of the Food Safety Modernization Act (FSMA) (Public Law 111-353) preventive controls section that modifies the Federal Food, Drug, and Cosmetic Act. It also will meet the requirement under the FDA Amendments Act (FDAAA) for processing standards for pet food. This rule establishes and implements hazard analysis and risk-based preventive controls for food for animals in addition to current good manufacturing practice in manufacturing, processing, packing, and holding of animal food. The rulemaking applies to domestic and imported animal food (including raw materials and ingredients) and is intended to build an animal food safety system for the future across all sectors of the animal food system.

This information collection request supports the reporting, recordkeeping, and third-party disclosure requirements associated with the final rule and codified in 21 CFR Part 507.

We request OMB approval for the following information collection provisions:

Reporting:

21 CFR 507.7; Exemption; submit attestation that facility is a qualified facility and attestation of preventive controls or compliance with State and Local laws (non-Federal)

21 CFR 507.67, 507.69 and 507.71; Submission of an Appeal, including Submission of a Request for a Formal Hearing

21 CFR 507.85; Requests for reinstatement of exemption

Recordkeeping:

Subpart A: General Provisions

21 CFR 507.7(e); Records demonstrating that the facility is a “qualified” facility

21 CFR 507.4(d); Animal food safety and hygiene training

Subpart C: Hazard Analysis and Risk-Based Preventive Controls

21 CFR 507.31-507.55; Food safety plan, including hazard analysis, preventive controls, and procedures for monitoring, corrective actions, and verification; recall plan; validation; reanalysis; modification; implementation records

Subpart E: Supply Chain Program

21 CFR 507.105-507.175; Written supply-chain program, including records documenting program

Subpart F: Requirements Applying to Records

21 CFR 507.200-507.215; General requirements, additional requirements applying to food safety plan, requirements for record retention, use of existing records, and special requirements applicable to written assurance

Third-Party Disclosure:

21 CFR 507.27(b); Labeling that the animal food product contains specific information and instructions

21 507.7(e)(1); Change labels on products with labels

21 CFR 507.7(e)(2); Change address on labeling (Sales Documents) for qualified facilities

21 CFR 507.25(a)(2); Animal food, including raw materials, other ingredients, and rework, is accurately identified

21 CFR 507.28(b); Holding and distribution of human food byproducts for use as animal food

* This information collection is not related to the American Recovery and Reinvestment Act of 2009.

2. Purpose and Use of the Information Collection

This rule requires animal food facilities to establish and implement hazard analysis and risk-based preventive controls, and implement current good manufacturing practices. The regulation includes requirements for animal food facilities to have a written food safety plan, including a hazard analysis; a description of preventive controls (including recall procedures); a description of monitoring procedures for those preventive controls identified; corrective action for any failure of the preventive controls; a description of verification procedures; and recordkeeping procedures. The information collection provisions are meant to ensure the safety of animal food in response to the FSMA and FDAAA statutory mandates.

Respondents to the information collection are owners, operators, or agents in charge of domestic or foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States.

3. Use of Improved Information Technology and Burden Reduction

Reporting requirements under the rule solicit what the agency believes is the minimal information necessary. At this time the information may be submitted to FDA either electronically or by mail, however we encourage electronic submissions. We are currently developing both paper and electronic forms to facilitate the reporting process and expect to make drafts available for comment in the near future. We expect most respondents will fulfill the recordkeeping requirements under the rule electronically where facilities may format their records in a manner they determine most appropriate.

4. Efforts to Identify Duplication and Use of Similar Information

Facilities may already maintain much of the information now required under the rule. As FDA has been Congressionally mandated to implement this rulemaking under FSMA, we believe that duplication of the information collection from another source is unlikely.

5. Impact on Small Business or Other Small Entities

Small businesses, defined as those with fewer than 500 employees, would not be subject to the requirements of this rule until 2 years after publication of the final rule. Very small businesses, defined as those facilities with gross annual sales of animal food of less than $500,000, adjusted for inflation, would not be subject to the requirements of this rule until 3 years after publication of the final rule.

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 on-farm activities conducted on low-risk animal food, are exempt from the hazard analysis and preventive controls requirements. Additionally, 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 comply with 21 CFR 113. Along with the very small businesses, other qualified facilities would also be exempt from the hazard analysis and preventive controls requirements of this rule, but would be subject to the requirements in subpart B (Current Good Manufacturing Practice).

Approximately 100% of respondents are private sector businesses.

6. Consequences of Collecting the Information Less Frequently

The information will be collected as often as required by the Hazard Analysis and Food Safety Plan of the respondents' facilities. 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.

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

FDA published a proposed rule in the *Federal Register* of October 29, 2013 (78 FR 64735), and published a supplemental notice of proposed rulemaking in the *Federal Register* of September 29, 2014 (79 FR 58475). The final rule issued September 17, 2015 (80 FR 56169). Comments received in response to the rulemaking are filed under Docket No. FDA- 2011-N-0922 and are addressed in the final rule (80 FR at 56331).

This rulemaking is the result of significant stakeholder engagement, beginning before the initial proposed rule. In response to extensive stakeholder input on the proposed rule, key provisions were revised in the supplemental notice of proposed rulemaking. After the supplemental notice of proposed rulemaking, more outreach was conducted to the stakeholder community to ensure that the risk-based, preventive requirements in this final rule are practical and protective of the public health.

9. Explanation of Any Payment or Gift to Respondent

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

10. Assurance of Confidentiality Provided to Respondents

This regulation does not specify 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

FDA estimates the burden associated with this final rule below. Our estimates are based on our experience with similar information collections and in consideration of feedback during rulemaking. More detailed information regarding our calculations may be found within the agency's Final Regulatory Impact Analysis (FRIA), Reference No. 60, under Docket No. FDA-2011-N-0922.

Reporting Burden

Table 1 shows the total estimated annual reporting burden associated with this final rule. This estimate is a revision from reporting estimates found in our proposed rulemaking, reflecting an updated count of the number of facilities registered with the Agency as animal food facilities, and resulting in an overall decrease from our previous estimate.

Table 1 – Estimated Annual Reporting Burden

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
507.7 exemption: submit attestation that facility is a qualified facility and attestation of preventive controls or compliance with State and local laws (non-Federal)	1,120	.5	560	.5	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

Out of 7,469 animal food facilities registered with FDA, we estimate approximately 15% (1,120) could be "qualified" facilities under the “very small business” definition as discussed in the FRIA (Ref. 60 of the final rule), and thus eligible for certain limited exemptions under the applicable regulations.

Section 507.5 exempts qualified facilities from subpart C and E of the regulations, which includes all of the hazard analysis and preventive controls requirements, including supply chain program requirements.

The number of respondents in row 1 is derived from agency estimates of the number of qualified animal food facilities that must report their status as such a facility every 2 years. The number of total annual responses is calculated by multiplying the number of respondents by the number of responses submitted annually. The average hourly time burden per response found in table 34, column 5 is based on FDA’s assumption that a facility will report its status electronically through a Web portal maintained by FDA, and that this will take approximately 0.5 hours (30 minutes).

The estimated burden associated with the requirements under §§ 507.67, 507.69, and 507.71 of the regulations is reflected in row 2. Based on the limited data on foodborne illness outbreaks originating at very small animal food facilities, FDA does not expect to withdraw many qualified

facility exemptions and expects the number of appeals to be even fewer. The estimated number of respondents is based on the Agency's expectation that the number of appeals will be very few. The number of responses per respondent reflects that the rule only requires one submission per appeal. Given that facilities must respond with particularity to the facts and issues contained in the withdrawal order, the agency estimates an average burden of 4 hours per response.

The estimated burden associated with the requirements under § 507.85(b) is reflected in row 3. The agency expects few, if any, requests for reinstatement of an exemption that has been withdrawn under the regulations and thus is providing an estimate of only 1 per year at this time. We estimate the time necessary for making such a request to be no more than 2 hours, which includes submitting the written request and presenting information that the animal food safety problems were adequately resolved and continued withdrawal of the exemption is not necessary to protect public (human and animal) health.

Recordkeeping Burden

Table 2 – Estimated Annual Recordkeeping Burden

21 CFR Section 507; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping	Total Hours
Subpart A – General Provisions					
507.7(e); records attesting that the facility is a "qualified" facility	1,120	.5	560	.1	56
507.4(d); documentation of animal food safety and hygiene training	7,469	0.75	5,579	0.05 (2 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, validation reanalysis, modifications, and implementation records.	7,469	519	3,876,411	.10	387,641
Subpart E – Supplier Program					
507.105-507.175; requirements to establish and implement program – including records documenting program	7,469	519	3,876,411	.10	387,641
Subpart F – Requirements Applying to Records					
507.200-507.215; 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	.10	387,641
TOTAL			11,635,372		1,163,258

Under the final rule, we estimate a total of 7,469 respondents (the number of registered animal food facilities) are subject to recordkeeping requirements found in the applicable regulations. Although FDA believes that, in some cases, all respondents will incur new recordkeeping activities as a result of the final rule, we believe other provisions may apply only to certain respondents (e.g., the manufacturer, holder, processor, distributor, etc.), depending upon the applicable regulation. With regard to the hazard-analysis and risk-based preventive controls, the supplier program, and the requirements applying to records under 21 CFR 507 subparts D, E, and F respectively, we have provided a cumulative estimated burden that we believe will be incurred by the respondents under this final rule. After allowing for implementation of the final rule and upon seeking reauthorization for its information collection provisions, FDA will reassess its burden estimate accordingly.

Third-Party Disclosure

Table 3 shows the estimated annual third-party disclosure burden associated with the final rule.

Table 3 – Estimated Annual Third-Party Disclosure Burden

21 CFR Section; Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Avg. 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	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	.01	1,030
507.28(b); holding and distribution of human food byproducts for use as animal food	40,798	2	81,596	0.25	20,399
Total					29,687

Under the final rule, we estimate all (7,469) respondents are subject to third-party disclosure requirements found in the applicable regulations. The number in column 2 represents an estimated annual number of those respondents we believe will incur third-party disclosure

burdens under the respective regulation shown in column 1. This figure is derived from our familiarity with third-party burden associated with similar FDA regulations. Upon implementation of the final rule, the Agency will reevaluate its estimate accordingly. To calculate the number of annual disclosures, we multiplied the number of respondents in column 2 by an estimated number of disclosures in column 3. This figure represents the estimated annual number of disclosures per respondent we attribute for the respective requirement. To calculate the annual hourly burden, we multiplied the number of annual disclosures by an estimated hourly burden in column 5. This figure represents the amount of time we attribute to conducting the respective disclosure activities identified in column 1.

Section 507.7(a)(2) provides that qualified facilities must either submit to FDA attestation of hazard identification, preventive controls implementation, and monitoring, or attestation that the facility is in compliance with applicable non-Federal food safety law.

Section 507.7(e) requires a qualified facility that chose the latter to notify consumers of the name and business address of the facility where the animal food was manufactured or processed (1) on the label if a package label is required by other provisions of the FD&C Act, or (2) on labeling if no label is required of the name and manufacturing address of the qualified facility.

Section 507.25(a)(2) provides that the management of the plant must ensure that animal food, including raw materials, other ingredients, or rework, is accurately identified during plant operations. (see 21 CFR 7.49, 7.42(b)(1) and (b)(2)).

Section 507.38(b)(1) and (b)(2) do not add to the estimated hourly burden because notification to consignees is already required when a facility initiates a recall under 21 CFR 7.49, and notification to the public is provided for under 21 CFR 7.42(b)(1) and (b)(2).

Under section 507.28(b), labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-product for use as animal food when distributed. The estimated number of disclosures per respondent and average burden per disclosure assumes that 60 percent of the 67,996 domestic human food manufacturing facilities (Ref. X) or 40,798 facilities are affected, and that two sets of labeling per facility per year will be required. We estimate 0.25 hours per disclosure to prepare labeling, and affix to the containers of labels, for a total of 20,399 burden hours.

12b. Annualized Cost Burden Estimate

Annualized Cost Burden Estimate[1]

Type of Respondent	Total Burden Hours	Hourly Wage Rate (including overhead)	Total Respondent Costs
Production worker (45%)	*526,067*	$22.61	$11,894,375
Industrial production manager (36%)	420,854	$58.07	$24,438,992
Lab technician (1%)	11,690	$23.03	$269,221

Type of Respondent	Total Burden Hours	Hourly Wage Rate (including overhead)	Total Respondent Costs
Clerk (4%)	46,762	$20.13	$941,319
First Line Supervisor (3%)	35,071	$34.26	$1,201,533
Consultant (5%)	58,452	$100	$5,845,200
TOTAL	1,169,038		$50,539,081

[1] Labor hours and wage rates were apportioned over the Standard Occupational Classification (SOC) codes using the Bureau of Labor Statistics (BLS) data for 2012 for NAICS 311100 – Animal Food Manufacturing.
[2]This table has a rounding error of plus 1 percent.

To calculate the total respondent cost, we multiplied the percentage of each category of labor classification by the total burden hours found in tables of section 12a. (1,169,038). We then added the respective labor costs.

13. Estimate 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

These activities will be covered by existing resource allocations. Therefore, we are estimating zero cost to the Federal government as a result of this rulemaking.

15. Explanation of Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Information is not to be published for statistical use.

17. Reason Display of OMB Expiration Date Is Inappropriate.

There is no reason not to display OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.