Current Good Manufacturing Practice and Hazard Analysis and
Risk-Based Preventive Controls for Food for Animals
OMB Control No. 0910-NEW
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 would establish and implement 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 will apply 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.

We request OMB approval for the following information collection provisions:

Reporting:

21 CFR 507.7; Facilities submit documentation 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

Recordkeeping:

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

21 CFR 507.25(a)(2); Labels of containers holding animal food, raw materials, or ingredients are labeled to correctly identify the contents

21 CFR 507.30; Food Safety Plan (including Hazard Analysis, Preventive Controls, Recall Plan, Monitoring procedures, Corrective Action procedures, Verification Procedures

21 CFR 507.39; Monitoring records

21 CFR 507.42; Corrective action records

21 CFR 507.45; Verification records (including reanalyzing food safety plans)

21 CFR 507.50; Records that document training for the qualified individual

Third-Party Disclosure:

21 CFR 507.25(a)(3); Labeling for the finished animal food product contains the specific information and instructions needed so the food can be safely used for the intended animal species

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

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

* 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 will require animal food facilities to establish and implement hazard analysis and risk-based preventive controls, and implement current good manufacturing practices. The regulation will include requirements for animal food facilities to have a written food safety plan, which will include 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. This 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

The proposed requirement that qualified facilities must report their status as such a facility every two years will likely be reported electronically through a web portal maintained by FDA.

4. Efforts to Identify Duplication and Use of Similar Information

Each manufacturer is responsible for its own recordkeeping. There are no other regulations at this time that require the submission or retention of this material, and thus the information collection is not duplicative.

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

The proposed rule published in the *Federal Register* on October 29, 2013 (78 FR 64735), and a supplemental notice of proposed rulemaking published in the *Federal Register* on September 29, 2014 (79 FR 58475).

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 for the information collection as follows:

Reporting Burden

Table 1 shows the estimated annual reporting burden associated with the proposed rule.

TABLE 1. – Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours	Capital Costs	O & M Costs
507.7(a); exemption: submit documentation demonstrating the facility is a qualified facility and documentation of preventive controls or compliance with State and local laws (non-Federal)	1,526	0.5	763	.5	381.5	$17,500	$17,500
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	$132	
TOTAL					385.5	$17,632	$17,500

Proposed sections 21 CFR 507.7, 507.67, 507.69, and 507.71 apply to qualified facilities. Section 507.5 of the proposed rule would exempt qualified facilities from the hazard analysis and preventive controls requirements. The number of respondents in Table 1 row 1 is derived from agency estimates of the number of qualified facilities, as described in the agency's Preliminary Regulatory Impact Analysis (PRIA) of the proposed and supplemental proposed rules (78 FR at 64818 and 79 FR at 58505). The latter co-proposes the definition of very small business (qualified facilities) as those facilities with gross annual sales of animal food of less than 1) $500,000 2) $1,000,000, or 3) $2,500,000 adjusted for inflation. This PRA analysis assumes a very small business definition of having less than $500,000 in total annual sales of animal food, adjusted for inflation.

The number of responses per respondent in Table 1, row 1 derives from the proposed requirement that qualified facilities must report their status as such a facility every two years. The average burden per response in row 1 is also derived from FDA's assumption that status will likely be reported electronically through a web portal maintained by FDA. FDA estimates this will take approximately .5 hours. For proposed section 507.69 in row 2, the estimate for the number of respondents (1) is based on the agency's expectation that the number of appeals will be very few. Because of the limited data of foodborne illness outbreaks 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 number of responses per respondent (1) reflects that the proposed 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 the average burden per response to be 4 hours. Four hours times $33.00 per hour for a compliance officer to prepare the appeal equals $132 annually. The number of total annual responses in Table 1 is derived by multiplying the number of respondents times the number of responses per respondent. Then, total burden hours are calculated by multiplying the total number of annual responses by the average burden per response.

Recordkeeping Burden

Table 2 shows the estimated annual recordkeeping burden associated with this information collection.

TABLE 2. – Estimated Annual Recordkeeping Burden

21 CFR Section; Activity	No. of Recordkeepers	No. of Records Per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping	Total Hours
507.7(e); records demonstrating that the facility is a "qualified" facility	1,526	.5	763	.1	76.3
507.25(a)(2); labels of containers holding animal food, raw materials, or ingredients are labeled to correctly identify the contents	330	312	102,960	0.01	1,030
507.30; food safety plan (including hazard analysis, preventive controls, recall plan, monitoring procedures, corrective action procedures, verification procedures)	6,603	1	6,603	27	178,281
507.42; corrective action records	6,603	2	13,206	1	13,206
507.39; monitoring records	6,603	1,562	10,313,886	.08	825,111
507.45; verification records (including reanalyzing food safety plan)	6,603	178	1,175,334	.12	141,040
507.50; records that document training for the qualified individual	6,603	1	6,603	.25	1,651
TOTAL					1,160,395

FDA obtained the total number of annual records by multiplying the number of recordkeepers by the number of records per recordkeeper. The total hours was calculated by multiplying the total annual records by the average burden per recordkeeping. The number of recordkeepers, the number of records per recordkeeper, and the average burden per record keeper were obtained from FDA's experience with similar recordkeeping requirements.

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[1]

21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours	Capital Costs
507.25(a)(3) Labeling for the finished animal food product contains the specific information and instructions needed so the food can be safety used for the intended animal species	330	10	3,300	.25	825	N/A
507.7(d)(1) Change labels on products with labels	1,526	4	6,104	1	6,104	$1,893,000
507.7(d)(2)Change address on labeling (Sales Documents) for qualified facilities	1,329	1	1,329	1	1,329	$61,000
Total					8,258	$1,954,000

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

For proposed section 507.25(a)(3), FDA estimates that 5% or 330 facilities will need to meet this requirement for the proposed rule. From the table above, 330 was multiplied by 10 disclosures (labeling) per respondent to calculate the total number of annual disclosures (3,300). The total number of hours was calculated by multiplying 15 minutes (.25 hours) per disclosure by the number of annual disclosures. The PRIA did not provide an individual cost figure for this labeling disclosure; however it indicated that the requirements were similar to assumptions used in an ERG model already developed and thus the basis of the agency's estimate.

Under proposed section 507.7(a)(2), qualified facilities must either submit to FDA documentation of hazard identification, preventive controls implementation, and monitoring, or documentation that the facility is in compliance with applicable non-Federal food safety law. Proposed section 507.7(d) would require 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 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. This results in additional hourly and cost burden as shown in Table 3. FDA assumed in the PRIA that all qualified facilities would choose to submit documentation that they are in compliance with the non-Federal food safety laws, and will therefore also need to include notification of the complete business address of the facility where the animal food was manufactured or processed.

Proposed section 507.38(b)(1) and (b)(2) does not add to the 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).

12b. Annualized Cost Burden Estimate

TABLE 4. – 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
General manager (7%)	81,833	$72.69	$5,948,441
Lab technician (1%)	11,690	$23.03	$269,221
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

Capital Costs	Operating and Maintenance Costs
$33,580,000	$38,139,334

As reported in the agency's PRIA, capital costs are estimated to be $100,740,000. We then averaged this figure over three years for an estimated annual cost of $33,580,000. Similarly,

estimated operating and maintenance costs are calculated to be $114,418,000. Dividing this figure by 3 then provides our annual estimation of $38,139,334. These figures represent costs that not reflected above and are associated with the establishment and implementation of the regulatory provisions discussed in the preamble of the proposed rulemaking.

14. Annualized Cost to the Federal Government

FDA estimates that it will require 10 full-time equivalent positions (FTEs) in the first year for development and implementation of the final rule and guidance, development and delivery of training, and other outreach activities. Based on the FY 2010 appropriation for the Center for Veterinary Medicine at FDA, the average cost of one of these employees is $213,000, including the cost of all overhead support of that FTE. The total cost of these ten employees in the first year would be $2.13 million. Additionally, FDA estimates that it would require $1.5 million in up front overhead costs. The total government cost in the first year for this rule would be $3.63 million.

In the second year, FDA estimates that an additional 3 FTEs would be required to manage the additional activities of the proposed rule. The 13 FTEs (the original 10 FTEs in FY 2012 plus the additional 3 FTEs in FY 2013) would cost $2.77 million in the second year.

Given the estimated number of affected facilities, the number of high risk facilities, and the required inspection frequencies defined in FSMA for both domestic and foreign facilities, FDA estimates that, at a minimum, about 40 FTEs would be required in the second year for inspection-related purposes of this rule. Based on the FY 2011 budget request for CVM inspection activities, the cost of an inspection-related FTE is about $194,000, including all overhead support of that FTE. Thus, FDA estimates that the cost of these 40 inspection-related FTEs would be about $7.76 million in the second year. In sum, FDA projects that total costs to FDA of this rule in the second year would be about $10.53 million.

Inspection-related costs are for foreign inspections for an additional 5 years. At that time, FDA expects that about 52 FTEs would be required for all inspection activities related to this rule. FDA estimates that these 52 FTEs would cost $10.09 million by the fifth additional year. Along with the original 13 FTEs for CVM implementation and management of the rule, FDA concludes that the proposed rule would add $12.86 million to agency costs in the fifth additional year.

The annualized cost over 10 years at a 7 percent discount rate for FDA enforcement activities is equal to $10.36 million ($10.59 million at a 3 percent discount rate).

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.