UNITED STATES FOOD & DRUG ADMINISTRATION

Animal Feed Regulatory Program Standards

OMB Control No. 0910-0760

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, the agency, us or we) implementation of its Animal Feed Regulatory Program Standards. The FDA Food Safety Modernization Act (FSMA), signed into law on January 4, 2011, provides FDA with tools to better protect public health by strengthening the human and animal food safety system. In the United States, Federal and State Government Agencies ensure the safety of animal feed. FDA is responsible for ensuring that all food and feed moving in interstate commerce, except those under the U.S. Department of Agriculture jurisdiction, are safe, wholesome, and labeled properly. States are responsible for conducting inspections and regulatory activities that help ensure food and feed produced, processed, and distributed within their jurisdictions are safe and in compliance with State laws and regulations. States primarily perform inspections under their own regulatory authority. Some States conduct inspections of feed facilities under contract with FDA. Because jurisdictions may overlap, FDA and States collaborate and share resources to protect animal feed.

The FDA Food Safety Modernization Act passed on January 4, 2011, calls for enhanced partnerships and provides a legal mandate for developing an Integrated Food Safety System (IFSS). FDA is committed to implementing an IFSS thereby optimizing coordination of food and feed safety efforts with Federal, State, local, tribal, and territorial regulatory and public health agencies. Model standards provide a consistent, underlying foundation that is critical for uniformity across State and Federal Agencies to ensure credibility of food and feed programs within the IFSS.

The program standards provide a uniform and consistent approach to feed regulation in the United States. Implementation of the draft feed program standards is voluntary. States implementing the standards will identify and maintain program improvements that will strengthen the safety and integrity of the U.S. animal feed supply. The feed standards are the framework that each State should use to design, manage, and improve its feed program. The standards provide for the following: (1) regulatory foundation; (2) training; (3) inspection program; (4) auditing; (5) feed-related illness or death and emergency response; (6) enforcement program; (7) outreach activities; (8) budget and planning; (9) assessment and improvement; (10) laboratory services; and (11) sampling program.
Each standard has a purpose statement, requirement summary, description of program elements, projected outcomes, and a list of required documentation. When a State program voluntarily agrees to implement the feed standards, it must fully implement and maintain the individual program elements and documentation requirements in each standard in order to fully implement the standard.

The feed standards package includes forms, worksheets, and templates to help the State program assess and meet the program elements in the standard. State programs are not obligated to use the forms, worksheets, and templates provided with the feed standards. Other manual or automated forms, worksheets, and templates may be used as long as the pertinent data elements are present. Records and other documents specified in the feed standards must be maintained in good order by the State program and must be available to verify the implementation of each standard. The feed standards are not intended to address the performance appraisal processes that a State agency may use to evaluate individual employee performance.

As set forth in the feed standards, available from our website at: https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/regulatory-program-standards/animal-feed-regulatory-program-standards-afrps, the State program is expected to review and update its improvement plan on an annual basis. The State program completes an evaluation of its implementation status at least every 3 years following the baseline evaluation by reviewing and updating the self-assessment worksheets and required documentation for each standard. The evaluation is needed to determine if each standard's requirements are, or remain, fully met, partially met, or not met. The State program revises the improvement plan based upon this evaluation.

Accordingly, we are requesting extension of OMB approval for the information collection provisions associated with our Animal Feed Regulatory Standards program as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

This information collection will be used by both FDA and the States to maximize the use of resources and better direct their regulatory activities to help ensure food and feed produced, processed, and distributed within their jurisdiction are safe and in compliance with State laws and regulations.

3. Use of Improved Information Technology and Burden Reduction

FDA estimates that 98 percent of the respondents will use electronic means to fulfill the agency's requirement or request. Current practices allow the reporting and recordkeeping requirements to be met through electronic means. The fill-in forms and worksheets will be in Portable Document Format (PDF), Excel or Word Format and available on the internet; they are fillable and fileable, but not signable.

4. Efforts to Identify Duplication and Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Business or Other Small Entities

FDA does not anticipate responses from small businesses and does not believe it will adversely affect small businesses or other small entities. The Animal Feed Standards do not impact business or small entities.

6. Consequences of Collecting the Information Less Frequently

Respondents will respond to the information collection on occasion, at least every three years. Collecting the information less frequently than that would degrade FDA's ability to measure progress and adjust resource allocations accordingly.

7. Consistency with the Guidelines in 5 CFR 1320.5

There are no special circumstances for this collection of this 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), FDA published a 60 day notice for public comment in the Federal Register of September 20, 2019 (84 FR 49524) to which the agency received one comment. However, this comment did not address the information collection as specified under the Animal Feed Regulatory Program Standards and was therefore not addressed.

9. Explanation of any Payment of Gift to Respondents

No gift or payment is offered to respondents for completing the information collection. The standards do correspond to a grant program that conforms to federal regulations. States can apply for a cooperative agreement allowing them to receive up to $300,000 each year for a period of five years to work toward significant conformance with the eleven standards. The States will conduct a baseline self-assessment and develop a strategic plan to fully implement the program standard in five years.

10. Assurance of Confidentiality Provided to Respondents

This ICR is not collecting personally identifiable information (PII) or other data of a personal nature. Information collected is about state animal food safety programs through the Animal Feed Food Regulatory Program Standards which ranges from information about state laws and regulations to procedures for dealing with foodborne illness outbreaks. Under the Freedom of Information Act (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 makes 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 of Sensitive Questions

This information collection does not include questions pertaining to sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Respondents to the information collection are State agencies seeking to avail themselves of the options described in the document. States agencies that conduct feed inspections under contract are interested in implementing the standards. The total estimated annual recordkeeping burden for implementation is 569 hours per respondent. The burden was determined by capturing the average amount of time for each respondent to assess the current state of the program and work toward implementation of each of the eleven standards contained in the animal food regulatory program standards (AFRPS). The hours per state feed regulatory program will average the same to account for continual improvement and self-sufficiency in the program. Our burden estimate reflects a decrease of 100,654 hours as a result of fewer respondents to the collection and a reevaluation of the time we ascribe for recordkeeping activities. This current burden is based on FDA's understanding that State agencies-maintained records of the usual and customary activities required by their inspection programs. The requested burden to the States for their implementation of the standards has been addressed and funding opportunities have been given to the States as an option for significant conformance of the eleven standards.

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

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

Type of Respondent	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
State Animal Feed Regulatory Program in the United States	34	1	34	569	19,346

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

12b. Estimated Annual Cost Burden

FDA assumes an average hourly wage rate of $15 per hour. Doubling this wage to account for overhead costs, we calculate respondent costs to $580,380 (19,346 x $30.00).

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

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

14. Annualized Cost to the Federal Government

The information collection itself will not incur any annualized cost to the federal government. States who opt into the standards may be awarded grants of up to $300,000 per year.

15. Explanation for Program Changes or Adjustments

This information collection reflects adjustment. Twenty-two (22) state animal feed regulatory programs are currently enrolled in the feed standards and there is a potential for total enrollment of thirty-four (34) states based on eligibility requirements for enrollment. The total estimated burden of this collection has decreased by 6 annual responses based on a reduction in recordkeepers from 40 to 34, as well as a decrease by 100,654 annual hours based on a reduction in the estimate for annual recordkeeping activities.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish the results of this information collection.

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

There are no reasons why display of the expiration date for OMB approval of information collection would be inappropriate.

18. Exception to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.