Animal Feed Regulatory Program Standards

OMB Control No. 0910-0760

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The FDA is requesting approval from the Office of Management and Budget (OMB) for information collection contained in the program standards. These collections are being performed to determine and develop inspection programs when jurisdiction overlaps between FDA and State agencies.

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. It enables FDA to focus on preventing human and animal food safety problems rather than reacting to problems after they occur. FSMA directs FDA to build an integrated national human and animal food safety system in partnership with Federal, State, local, territorial, and tribal authorities, explicitly recognizing that all human and animal food safety agencies need to work together in an integrated way to achieve national public health goals. FSMA identifies some key priorities in working with partners in areas, such as: reliance on Federal, State, and local agencies for inspections; improving foodborne illness surveillance; and leveraging and enhancing State and local human and animal food safety and defense capacities. In addition, FSMA specifically authorizes grants to certain entities to enhance human and animal food safety.

FSMA Section 201 allows FDA to rely on partner agencies to meet the inspection mandate called required in FSMA. FSMA Section 205(c)(1) allows FDA to develop and implement strategies to leverage and enhance the food safety and defense capacities of State and local agencies in order to achieve the following goals: (1) strengthen the capacity of State and local agencies to carry out inspections and enforce safety standards and (2) improve the effectiveness of Federal, State, and local partnerships to coordinate food safety and defense resources and reduce the incidence of foodborne illness.

National program standards for retail food, manufactured food, and animal feed are currently used to leverage and enhance the food safety and defense capacities of State and local agencies. Implementation of national regulatory program standards will build a platform for mutual reliance between partner agencies in Federal and State governments.

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

The information described is not duplicative and must be obtained from the States.

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 4/12/2016 (81 FR 21578) 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.

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

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 will make 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

The most likely respondents to this information collection will be 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 reporting burden for implementation is 3000 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 AFRPS. The hours per respondent will average the same to account for continual improvement and self-sufficiency in the program.

From the State program perspective, the annual recordkeeping costs documenting conformance to the program standards would be the same as for the State program

maintaining records of the usual and customary activities required by its inspection program.

FDA estimates the burden of this collection of information as follows:

Table 1.—Estimated Annual Recordkeeping Burden

Type of Respondent	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
State Employee	40	1	40	3000	120,000

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

In 2014, this ICR was approved for a burden of 150,000 hours. This was calculated based on 50 respondents (50 States) with an average of 3000 recordkeeping hours for each. Since then, FDA has enrolled 40 States in the program, with the average recordkeeping burden remaining the same. This change accounts for the decrease in the "No. of Recordkeepers" and "Total Hours" (120,000) shown in Table 1.

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.