Animal Feed Regulatory Program Standards
0910-NEW
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 food safety system. It enables FDA to focus on preventing food safety problems rather than reacting to problems after they occur. FSMA directs FDA to build an integrated national food safety system in partnership with Federal, State, local, territorial, and tribal authorities, explicitly recognizing that all 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 food safety and defense capacities. In addition, FSMA specifically authorizes grants to certain entities to enhance food safety.

FSMA Section 201 allows FDA to rely on partner agencies to meet the inspection mandate established 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.

Model standards for retail food and manufactured food are currently used to leverage and enhance the food safety and defense capacities of State and local agencies.

At this time, model regulatory program standards do not exist for animal feed. The draft feed standards are a major step in a long-term process of collaboration to achieve uniformity and consistency in feed safety across the nation while acknowledging State

responsibilities and authorities. Implementation of model 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 achieve uniformity and consistency in feed safety across the nation while acknowledging State responsibilities and authorities.

3. Use of Improved Information Technology and Burden Reduction

FDA anticipates 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 are available in WORD format.

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 the Animal Feed Regulatory Program Standards (hereafter known as feed standards) will adversely affect small businesses or other small entities. The feed standards do not impact small business or small entities.

6. Consequences of Collecting the Information Less Frequently

FDA will review the information collection if the State feed program receives financial assistance from the Agency to implement the feed standards.

The State program reviews and updates its improvement plan on an annual basis. At least every three years, the State program completes an 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.

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to 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 7/10/2013 (78 FR 41401). Four comments were received. Three comments pertain to the information collection. One comment addressed an issue unrelated to the proposed collection of information, such as pet food safety. Therefore, we do not address this issue in this document.

One comment expressed concern that the estimated hours to collect the information required to implement and maintain the requirements in the draft feed standards is low. Two comments expressed concern that implementing and maintaining the draft feed standards would require more State program employees and financial support from FDA.

Regarding the comment asserting that the total estimated hours reported is low; we recognize the number of hours needed to implement and maintain the draft feed standards will vary among States depending on the size of the State's feed program, the number of staff, and the State's short and long term goals for implementing the draft feed standards. The burden estimates are reasonable given the variation among State programs and their current ability to implement the draft feed standards.

Regarding the comment expressing concern that the State feed programs would need additional employees and funding from FDA to implement and maintain the requirements in the draft feed standards; FDA recognizes that State feed programs may need additional resources to implement and maintain the draft feed standards. Therefore, FDA will pursue funding for the draft feed standards; however, the level of funding may vary each year and is contingent on budget approval.

9. Explanation of any Payment of Gift to Respondents

Although FDA plans to provide financial support to the State programs that implement the feed standards, funding opportunities are contingent upon the availability of funds. Funding opportunities may be only available to State programs that currently have an FDA feed inspection contract. State programs receiving financial support to implement the program standards will be audited by FDA.

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 burden has been calculated to 3,000 hours per respondent. The estimate includes time for reviewing the standards, gathering and maintaining the data and documents for each standard, and completing and reviewing the data and documents that would be spent to fully implement the 11 standards. FDA recognizes that full use and implementation of the feed standards by State programs will occur over many years and the number of years to fully implement the feed standards will vary among States. This burden was determined by averaging the burden estimates received from five respondents. The five respondents are representative of the State feed programs in the United States.

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

Table 1-Estimated Annual Recordkeeping Burden

Respondent	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
State Feed Regulatory Programs in the United States	50	1	50	3,000	150,000

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

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

14. Annualized Cost to the Federal Government

FDA will offer financial support to State programs that implement the feed standards; however, funding opportunities are contingent upon the availability of funds. Funding for implementation of the feed standards will be offered in the State feed contract. The structure for this funding will replicate the MFRPS funding structure, such that the first year will be a pilot and will consist of a limited number of states receiving funding via a contract. This will allow the states an opportunity to learn more about the AFRPS within a lower risk funding vehicle. In the first year, a State will be offered $10,000. The estimated annual cost to the Federal Government will not exceed $150,000 for the first year, which is similar to the funding levels managed during the pilot phase of the MFRPS. In the second year of implementation, a State may be awarded up to $300,000 per year for five years through a cooperative agreement. The estimated annual cost to the Federal Government for years two through five will not exceed $10,800,000 per year.

15. Explanation for Program Changes or Adjustments

This is a new collection.

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

Not applicable.

18. Exception to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.