UNITED STATES FOOD & DRUG ADMINISTRATION

Federal-State 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 Federal-State Regulatory Program Standards. The existing information collection related to the Animal Feed Regulatory Program Standards (AFRPS) remains unchanged. We are establishing regulatory program standards for eggs and have developed the "Egg Regulatory Program Standards" (ERPS). Therefore, we are seeking approval to revise this information collection to add the ERPS and its information collection provisions.

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 human and animal food. 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 human or animal food facilities under contract with FDA. Because jurisdictions may overlap, FDA and States collaborate and share resources to protect human and animal food.

FSMA 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 human and animal food programs within the IFSS.

The program standards provide a uniform and consistent approach to human and animal food regulation in the United States. Implementation of the draft 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. human and animal food supply. The standards are the framework that each State should use to design, manage, and improve its program. The

AFRPS provide for the following eleven standards: (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.

Similarly, the ERPS provide for the following ten standards: (1) regulatory foundation; (2) training; (3) inspection program; (4) inspection audit program; (5) egg-related illness, outbreak and emergency response; (6) compliance and enforcement program; (7) outreach activities; (8) program resources; (9) program assessment; and (10) laboratory support.

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 standards, it must fully implement and maintain the individual program elements and documentation requirements in each standard to fully implement the standard.

For each regulatory standards program, a 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 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 standards must be maintained in good order by the State program and must be available to verify the implementation of each standard. The standards are not intended to address the performance appraisal processes that a State agency may use to evaluate individual employee performance. The AFRPS are 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-and-preventive-controls-cooperative-agreement-program. As set forth in the standards, the State program is expected to review and update its improvement plan on an annual basis. At least every year, the State program reviews and updates 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 OMB approval for the information collection provisions associated with our Federal-State Program Regulatory Standards 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 99 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 and Egg Regulatory Program 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 and/or annually. 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 May 14, 2021 (86 FR 26528). No public comments were received in response to the notice.

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 annual grant funds for a period of five years to work toward significant conformance with the 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 food safety programs through the AFRPS and ERPS, which range 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 animal feed or egg safety inspections under contract are interested in implementing the standards.

Animal Food Regulatory Program Standards

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 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. This current burden is based on FDA's understanding that State agencies maintain 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 standards.

Egg Regulatory Program Standards (ERPS)

Ten (10) egg regulatory programs are currently enrolled in the egg regulatory program standards and there is a potential for total enrollment to increase. The total estimated annual recordkeeping burden for implementation (recordkeeping and submission of data elements to FDA) is 500 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 ten standards contained in the egg regulatory program standards (ERPS). The hours per egg regulatory program will average the same to account for continual improvement and self-sufficiency in the program.

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

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

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
State, Local, Territorial, and/or Tribal Governments: submission of data elements consistent with Animal Feed Regulatory Program in the United States	34	1	34	569	19,346
State, Local, Territorial, and/or Tribal Governments; submission of data elements to FDA consistent with Egg Regulatory Program in the United States	10	10	100	50	5,000
	44	-	134	619	24,346

[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 $53.68 per hour. We calculate respondent costs to $1,306,893.28 (24,346 x $53.68).

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 for the AFRPS and $200,000 for the ERPS).

15. Explanation for Program Changes or Adjustments

This information collection request reflects a program change revision. The total estimated burden of this collection has increased by 5,000 burden hours, from 19,346 to 24,346 burden hours.

Based on our experience with similar information collection, we estimate an initial 10 respondents will participate in the ERPS, and assume an average of 50 burden hours per response is necessary for the attendant recordkeeping and submission of data elements to FDA. We expect participation in the ERPS to increase. Finally, upon submission of the Information Collection Request, we are correcting an inadvertent calculation error in the total burden hours as displayed on page 26530, in Table 1, in our 60-day notice in the *Federal Register* of May 14, 2021 (86 FR 26528).

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.