U.S. Food and Drug Administration
Manufactured Food Regulatory Program Standards
OMB Control No. 0910-0601

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food Safety Modernization Act (FSMA) (P.L.111-353) 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 human and animal food 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 human and animal food 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.

Section 205(c) of FSMA (codified in 21 U.S.C. 2224) 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 human and animal food 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.

As part of this effort, we have initiated programs that include developing and instituting regulatory standards intended to reduce the risk of foodborne illness through coordinated efforts with our strategic partners. Regulatory program standards establish a uniform foundation for the design and management of State, local, tribal, and territorial programs that have the responsibility for regulating human and animal food. There are no changes to the existing program standards. Partnering with other regulatory officials also helps maximize limited resources in administering FDA regulations pertaining to the manufacturing/processing, packing, or holding of manufactured food for consumption in the United States.

We therefore request OMB approval of the information collection contained in the Manufactured Food Regulatory Program Standards (MFRPS).

2. Purpose and Use of the Information Collection

This information collection is used by both FDA and the states to maximize the use of resources and better direct their regulatory activities to help ensure food manufactured, processed, packed, or held for consumption in each jurisdiction is safe and in compliance with state laws and regulations.

The regulatory program standards provide a uniform and consistent approach to manufactured food regulation in the United States. States may implement the program standards on a voluntary basis. The MFRPS is the framework that each participating state should use to design, manage, and improve its manufactured food regulatory programs. The MFRPS provide for the following ten standards: (1) regulatory foundation; (2) training program; (3) inspection program; (4) audit program; (5) food-related illness, outbreak, and hazards response; (6) compliance and enforcement program; (7) outreach activities; (8) program resources; (9) program assessment; and (10) laboratory support. There are no changes to the existing program standards.

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. We invite you to visit our website (FDA Regulatory Program Standards) for more information.

The MFPS includes appendices to help the state program assess and meet the program elements in the standards. State programs are not obligated to use the appendices 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 current and fit for use and must be available to verify the implementation of each standard. As set forth in the standards, the state program is expected to develop or update a strategic improvement plan that aids the state program in achieving and maintaining conformance with the program elements of each standard and addresses any necessary corrective actions.

3. Use of Improved Information Technology and Burden Reduction

The FDA estimates that 100 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 fillable appendices will be in Portable Document Format (PDF), Excel or Word Format and available on the internet. The MFRPS is publicly available for download at the FDA's Regulatory Program Standards website and questions may be directed to FDA through dedicated e-mail.

4. Efforts to Identify Duplication and Similar Information

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

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 MFRPS do not impact business or small entities.

6. Consequences of Collecting the Information Less Frequently

Collecting the information solicited in this collection less frequently would negatively impact FDA's ability to evaluate annual grantee performance. The annual collection is proportionate and appropriate.

There are no technical or legal obstacles to the collection of this information.

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 June 16, 2025 (90 FR 25309). No comments were received.

The FDA works closely with state agencies participating in the MFRPS program through the AFDO MFRPA Board to review and evaluate the program standards. There were no changes made to this version of the MFRPS. The program standards are the result of external collaboration and coordination between FDA and the Association of Food and Drug Officials (AFDO) Manufactured Food Regulatory Program Alliance (MFRPA). We consider any formal comments received on the previous edition of these program standards and feedback obtained from our collaboration with the states.

9. Explanation of any Payment or 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.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974 [5 U.S.C. 552a]

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although this ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted via the Manufactured Food Regulatory Program Standards (MFRPS) Appendices 10.5.1 through 10.5.6.5 is name, email address, and business address. We have determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, the FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and/or webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under 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 (see 21 CFR 20), 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 sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Table 1 -- Estimated Annual Reporting Burden[1,2]

Type of Respondent; Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
State Governments; Maintenance of data records consistent with the MFRPS	42	1	42	569	23,898

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals may not sum due to rounding.

Table 2 -- Estimated Annual Recordkeeping Burden[1,2]

Type of Respondent; Information Collection Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
State Governments; Maintenance of data records consistent with the MFRPS	42	10	420	40	16,800

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals may not sum due to rounding.

One state program is no longer participating in the MFRPS and two enrolled state agencies have been reorganized into one state agency since our last evaluation.

12.b. Annualized Cost Burden Estimate

FDA assumes an average hourly wage rate of $43.55 per hour. Doubling that to approximate a "fully loaded" cost estimate produces $87.10/hr. We therefore calculate respondent costs to be $3,544,795.80 (40,698 x $87.10). [1]

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

[1] Per U.S. Bureau of Labor Statistics May 2023 National Occupational Employment and Wage Estimates – Mean hourly wage for Business and Financial Operations occupations: https://www.bls.gov/oes/current/oes_nat.htm#13-0000

Costs

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

14. Annualized Cost to the Federal Government

Staff needs specific to this collection include effort to review report submissions, provide technical guidance to program participants on using the forms, and facilitation of periodic review and updates to the MFRPS when needed.

Table 2.--Estimated Government Costs Using the 2025 Salary Tables			
Government Personnel	Effort Commitment	Average Annual Salary	Total Costs
GS-12 (1)	5%	$101,401	$5,070.05
GS-13 (6 @ 25% each)	150%	$120,579	$180,868.50
GS-14 (1)	10%	$142,488	$14,248.80
GS-15 (1)	5%	$167,603	$8,380.15
Total			$208,567.50

15. Explanation for Program Changes or Adjustments

One State program is no longer participating in the MFRPS and two enrolled state agencies have been reorganized into one state agency since our last evaluation. Due to the decrease in respondents, the total estimated burden for this collection has decreased by 1,938 hours.

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.