Manufactured Food Regulatory Program Standards
OMB Number 0910-0601
SUPPORTING STATEMENT

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. Additionally, the information collection is needed to implement a change in FDA's oversight of State contracts that was recommended by the Department of Health and Human Services' Office of the Inspection General in its report dated June 2000[1]. The collection of this information is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

Abstract

The elements of the manufactured food regulatory program standards are intended to ensure that the States have the best practices of a high-quality regulatory program to use for self-assessment and continuous improvement and innovation. The ten standards describe the critical elements of a regulatory program designed to protect the public from foodborne illness and injury. These elements include the State program's regulatory foundation, staff training, inspection, quality assurance, food defense preparedness and response, foodborne illness and incident investigation, enforcement, education and outreach, resource management, laboratory resources, and program assessment. Each standard has corresponding self-assessment worksheets, and certain standards have supplemental worksheets and forms that will assist State programs in determining their level of conformance with the standard. When finalized, FDA will use the program standards as a tool to improve contracts with State agencies. The program standards will assist both FDA and the States in fulfilling their regulatory obligations.

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 at reducing foodborne illness hazards in firms that manufacture, process, pack, or hold foods.

[1] Office of Inspector General, *FDA Oversight of State Food Firm Inspections: OEI-01-98-00400* (Department of Health and Human Services, 2000), p. 5.

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) and available on the internet.

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.

6. Consequences of Collecting the Information Less Frequently

The information collection will be reviewed after the State has completed their self-assessment and improvement plan at the following intervals: 12-18 months, 36 months, and 60 months and will only impact the small number of States that have availed themselves of this option.

FDA conducts a program assessment validation audit (hereafter known as validation audit). The validation audit should occur within 18 months. A subsequent validation audit will be conducted at 36 months to evaluate the State's progress toward fully implementing the standards. Then, at 60 months, FDA will conduct a comprehensive program audit. As part of the program audit, the auditor reviews the records and supporting documents required by the criteria in each standard to determine if the self-assessment and improvement plan accurately reflect the State program's level of conformance with each of the standards.

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 12/02/2009 (74 FR 63154). No comments were received.

FDA conducts a quarterly conference call with the 50 States and hosts a 50-state meeting each year. State program managers participate in this call. This is an open discussion among FDA and the States about Federal-State issues. FDA solicits comments annually on its offer of work under contract with the States.

9. Explanation of any Payment of Gift to Respondents

The implementation of the program standards will be negotiated as an option for payment under the State food contract. States that are awarded this option will receive up to $25,000 over a period of five years. The States will conduct a baseline self-assessment and 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

The most likely respondents to this information collection will be State agencies seeking to avail themselves of the options described in the document.

The total estimated annual reporting burden for implementation is 40 hours per respondent, and for the baseline self-assessment an additional 160 hours.

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 Reporting Burden[1]				
No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
44	1	44	40	1760

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

Table 2.--Estimated First-Year Baseline Self Assessment Burden[1]				
No. of Respondents	First-Year Frequency per Response	Total First-Year Response	Hours per Response	Total Hours
17	1	17	200	3400

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

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

There are no capital costs or operating maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

The total cost to the Federal Government will vary, because the number of States that are awarded the option will vary. When the option is award, the cost to the Federal government will be $25,000 per State program. A State program will receive $5,000 each year for five years. At this time, FDA has 44 contracts with State programs. If each contractor is awarded the option for five years, the total cost burden to the Federal Government would be $1,100,000.

It is estimated that the cost to FDA to inclusively oversee the State food contract inspection programs would exceed the cost to reimburse the States for implementing and maintaining an inspection program comparable to FDA.

15. Explanation for Program Changes or Adjustments

This adjustment between current burden and requested burden is a result increase in the number of hours needed to compile records. This current burden was based on FDA's understanding that State agencies maintained records of the usual and customary activities required by their inspection programs.

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 statement identified in Item 19 of OMB Form 83-I.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods employed in this collection of information are needed to determine a rate of performance.

List of Attachments

Attachment A Manufactured Food Regulatory Program Standards