Manufactured Food Regulatory Program Standards
OMB Number 0910-0601
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. 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 reports dated June 2000[1] and December 2011[2] regarding training and audits.

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.

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.

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

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

[2] Office of Inspector General, *Vulnerabilities in FDA's Oversight of State Food Facility Inspections: OEI-02-09-00430* (Department of Health and Human Services, 2011)

FDA does not anticipate responses from small businesses and does not believe it will adversely affect small businesses or other small entities. The Manufactured Food Standards do not impact business or 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 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. The State conducted the verification audit to determine if it properly assessed its food inspection program against the manufactured food regulatory program standards. The validation audit conducted by FDA, now replaces the verification audit that was previously conducted by the State.

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 2/19/2013 (78 FR 11651). 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 these calls and participates in the 50-state meeting. 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 can 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. States can also 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 ten 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 food inspections under contract are interested in implementing the standards.

The total estimated annual reporting burden for implementation is 303 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 MFRPS. 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 REPORTING BURDEN

: Respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
State Departments of Agriculture or Health	44	1	44	303	13,332

13. Estimates 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 information collection.

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. Under option one, the cost to the Federal government will be $25,000 per State program spread evenly over five years ($5,000 each year). If available, option two awards "up to $300,000 per year" for five years through a cooperative agreement that states can apply using www.grants.gov. At this time, FDA has 44 contracts with State programs and every state is not enrolled in the standards. Five states have the $5,000 option on their contract and 26 states have the " up to $300,000 per year" cooperative agreement award. The total cost burden to the Federal Government could be approximately $39,125,000.00.

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. 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 ten standards.

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.