

**SUPPORTING STATEMENT
FOR
The Manufactured Food Regulatory Program Standards
Docket Number 2006D-0246
OMB Number 0901-0601
Expires 5/31/2010**

A. BACKGROUND

The Manufactured Food Regulatory Program Standards (hereafter known as program standards) provide a uniform foundation for the design and management of State programs responsible for the regulatory oversight of plants that manufacture, process, pack, or hold foods in the United States. Use of the standards will result in new collections of information. In order to conform to the program standards, the State program will conduct a self-assessment of its current program. The program standards will be used by the Food and Drug Administration (FDA) and the State agency to measure equivalency by assessing the critical elements of the State program. Additionally, the program standards have corresponding forms and worksheets for use by State programs that lack alternate forms equivalent to the forms and worksheets in the program standards.

B. JUSTIFICATION

1. Circumstances Necessitating Information Collection

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 that are equivalent in effect, particularly 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 Inspector General in its report dated June 2000¹.

2. By Whom and for What Purpose the Information is to be Used

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. Consideration of Information Technology

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 Already Available

The information described is not duplicative.

5. Impact on Small Business or Other Small Entities

FDA does not believe that the collection of information will adversely affect small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently and Technical or Legal Obstacles

The information collection will be reviewed every 24 months as part of FDA's oversight of State contracts and will only impact the small number of States that have availed themselves of this option.

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

7. Consistency with the Guidelines in 5 CFR 1320.5(d)(2)

This information collection is consistent with 5 CFR 1320.5(d)(2).

8. Consultation Outside the Agency

On July 20, 2006 (71 FR 41221), FDA published a Notice of Availability for the Draft Manufactured Food Regulatory Program Standards asking for comments on the information collection. (Attachment B). FDA received a number of comments on the draft program standards; however, only two letters of comment included comments regarding the information collection provisions. An additional letter supported the comments provided in one of the two letters of comment.

FDA conducts a quarterly conference call with the 50 States. 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. In April 2007, FDA will meet with officials from the States with food contracts. The purpose of this meeting is for the agency to discuss the program standards

and to solicit information and comments from interested persons on how the Program Standards will be implemented by 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 contract. States that are awarded this option will receive up to \$5,000 to perform the self assessment and to maintain an operational plan for self improvement.

10. Assurance of Confidentiality Provided to Respondent

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. Estimate of Hour Burden Including Annualized Hourly 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 800 hours, and for the improvement plan an additional 200 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.

This estimate was obtained as follows.

Table 1. Estimated Annual Reporting Burden¹

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
40	0.5	20	40	800

¹Because State agencies already keep records of the usual and customary activities required by their inspection programs, the burden from compiling these records is not included in the burden chart.

Table 2. Estimated Annual "Improvement Plan" Burden

<u>No. of Respondents</u>	<u>Annual Frequency per Response</u>	<u>Total Annual Responses</u>	<u>Hours per Response</u>	<u>Total Hours</u>
<u>40</u>	<u>1</u>	<u>40</u>	<u>5</u>	<u>200</u>

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13. Estimate of the Other Total Annual Cost Burden to Respondents or Recordkeepers

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 \$5,000. At this time, FDA has 40 contracts with State programs. If each contractor is awarded the option, the total cost burden to the Federal Government would be \$200,000.

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

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 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

Attachment B Federal Register of July 20, 2006 (71 FR 41221)