SUPPORTING STATEMENT

ADOPTION OF THE FDA FOOD CODE BY LOCAL, STATE AND TRIBAL GOVERNMENTS

OMB No. 0910-0448

A. JUSTIFICATION

1. Need and Legal Basis

FDA has developed its model Food Code to assist and promote consistent implementation of national food safety regulatory policy among the local, State, and tribal governmental agencies that have primary responsibility for the regulation or oversight of retail level food operations. The FDA Food Code provides a scientifically sound technical and legal basis for regulating the retail segment of the food industry. Authority for providing such assistance is derived from section 311(a) of the Public Health Service Act (42 U.S.C. 243(a)) (Attachment A). Under 31 U.S.C. 1535, FDA provides assistance to other Federal agencies such as the Indian Health Service.

Nationwide adoption of the model FDA Food Code is an important step toward the agency's goal for consistent, scientifically sound, and risk-based food safety standards and practices. A current, comprehensive, and accurate inventory of food code adoptions by States and U.S. territories, local, and tribal governments is necessary to determine the status of up-to-date protection of the U.S. population and to identify areas where assistance to these governments may promote the adoption of regulations based on the FDA Food Code.

This collection effort, which began in 2001, has had remarkable success with 97 percent participation from State and territorial governmental agencies. FDA contracted with the Association of Food and Drug Officials (AFDO) to conduct the initial survey using the OMB approved survey form. The rulemaking process that local, State, territorial, and tribal governmental agencies must follow to adopt the model FDA Food Code is often a long and complicated process that can extend for several years. For this reason, many agencies have reported that they are still in the rulemaking process to adopt or update their food codes. Thus, FDA believes that extension of OMB approval of the survey is needed in order to keep the current database accurate and up-to-date. AFDO will collect the information electronically and/or telephonically and will be able to provide respondents with previous survey responses already in the database.

FDA requests extension of OMB approval for the collection of information from local, state and tribal governments regarding the adoption of the FDA Food Code, using the attached questionnaire (Attachment B).

2. Information Users

Nationwide adoption of the model FDA Food Code is an important step to achieve uniformity and consistent food safety practices and standards that are scientifically sound and risk-based and allows FDA to work more effectively with partners in state, local and tribal governments and with other federal agencies. To help achieve these aims, FDA needs a comprehensive, current and accurate inventory of Food Code adoptions around the country to monitor the effectiveness of FDA's assistance to these agencies and to identify gaps where additional assistance may be needed.

FDA has contracted with AFDO to contact local, state and tribal officials to obtain information about the status of Food Code adoptions in their respective jurisdictions. Telephonic and electronic means have been used since 2001 when the project began using the OMB approved information collection form. AFDO compiles this information in an active data base and produces quarterly reports on the nationwide progress towards adoptions of the Code. Results are posted on the FDA web site (http://www.cfsan.fda.gov) and are updated quarterly as new information is gathered by AFDO. The information is used by FDA to track the adoptions of local, state and tribal codes/regulations patterned after the FDA Food Code.

3. Improved Information Technology

Response to this project has been excellent with a 97% response rate from the agencies contacted. The experience gained since 2001 has further reduced the number of agencies to be contacted and the types of information to be gathered. Collections of information are electronically and/or telephonically obtained providing the respondents with data already in the data base to further ease the response and lower the burden. Results are posted in tabular and graphic formats on the FDA web site with quarterly updates as new data are received.

4. Duplication of Similar Information

FDA is unaware of any comprehensive inventory of Food Code adoptions from other sources. There are no similar data that can be used or modified for use. No public comments were received that identified any other sources. Thus, there is no duplicative collection of information.

5. Small Businesses

No small businesses will be involved in this collection.

6. Less Frequent Collection

Without this data collection, FDA would not have an accurate inventory of Food Code adoptions throughout the United States and would be unable to accurately measure progress toward the goal of nationwide adoption. The information allows FDA to identify areas where additional assistance to adopting agencies is needed and allocates resources to meet those needs.

Nationwide adoption is necessary to achieve the goal of uniform, scientifically sound and risk-based standards that are beneficial to the food industry and consumers.

7. Special Circumstances

This information collection does not contain any special circumstances. The collection fully complies with 5 CFR 1320.5(d)(2).

8. *Federal Register* Notice/Outside Consultation

In accordance with 5 CFR 1320.8(d), in the Federal Register of January 26, 2007 (72 FR 3862), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received no comments that were responsive to the comment request.

9. Payment/Gift to Respondent

Respondents do not receive any type of payment or gift for responding to the request for information.

10. Confidentiality

This information collection does not request any information of a personal nature, or trade secret or commercial confidential information. The information to be provided is public in nature. Thus, FDA provides no assurances of confidentiality.

11. Sensitive Questions

No questions of a sensitive nature are included in collection of information from local, state and tribal governments regarding the adoption of the FDA Food Code.

12. Burden Estimate (Total Hours and Wages)

Description of Respondents: States and U.S. territories, local, and tribal governmental agencies.

The total estimated annual burden for this collection of information is 300 hours. FDA estimates the burden of this collection of information as follows:

Table 1. – Estimated Annual Reporting Burden[1]

Food Code Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Respondents	75	4	300	1	300

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

information.

This estimate is based on FDA's experience and the number of updates received in the past 3 years. FDA has reduced the estimated number of annual respondents from 150 to 75. FDA estimates that 75 respondents will provide four quarterly updates each, resulting in an estimated 300 total annual responses. The agency estimates that each quarterly update will take about 1 hour. Of the 75 respondents, those who amend their regulations with changes unrelated to the risk factors and interventions, and those who are not adopting model FDA Food Code provisions, but are incorporating certain Conference for Food Protection recommendations only, will likely need only annual contact.

Costs to Respondents. FDA estimates that the average hourly wage is $15 per hour. Doubling this wage to account for overhead costs, FDA estimates the hourly cost to respondents to be $30. The overall estimated cost incurred by the respondents is $9,000 (300 burden hours X $30/hr = $9,000).

13. Capital Costs (Maintenance of Capital Costs)

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

14. Cost to the Federal Government

The estimated annual cost to the Federal Government for this information collection is $24,999 for AFDO to contact, collect, collate and periodically report results to FDA.

15. Program or Burden Changes

The total annual hour burden has decreased from 600 hours to 300 hours. This decrease is due to a decrease in the estimated number of respondents. Also, please note that although the information collection questionnaire has increased from five questions to seven questions, FDA has not changed its estimate of the hours per response. FDA estimates that it will still take the respondent one hour or less to respond to the seven questions.

16. Publication and Tabulation Dates

Due to the lengthy adoption process required in most jurisdictions, the project continues to be a long-term effort with periodic updates to the data base prepared by AFDO under annual contract with FDA. Quarterly status reports from AFDO are submitted to FDA for placement on FDA’s Internet web site which includes tabular and graphic data such as maps color-keyed to portray the status of adoptions nationwide. AFDO also provides special analysis from the data base to FDA to aid in assisting States, local and Tribal Nations efforts to adopt the Food Code.

17. Display of OMB Approval Date

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to "Certification for Paperwork Reduction Act Submissions"
N/A