SUPPORTING STATEMENT

VOLUNTARY NATIONAL RETAIL FOOD REGULATORY PROGRAM STANDARDS

OMB No. 0910-[ ]

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

While the responsibility for regulating retail and foodservice establishments lies primarily with state, local, and tribal jurisdictions, FDA provides assistance to these jurisdictions through multiple means including, but not limited to, training and technical assistance. Authority for providing such assistance is derived from section 311 of the Public Health Service Act (42 U.S.C. 243). In addition, FDA's mission under section 903(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 393(b)(2)(A)) includes ensuring that foods are safe, wholesome, and sanitary, and section 903(b)(4) of the Act directs FDA to cooperate with food retailers, among others, in carrying out this part of its mission.

The Centers for Disease Control and Prevention has identified the major contributing factors associated with foodborne illness outbreaks. Five of these contributing factors directly relate to retail and foodservice establishments and are called "foodborne illness risk factors" by FDA. In an effort to assist state, local, and tribal regulators and the retail and food service entities they regulate, FDA has developed a Program Standards document entitled, "Voluntary National Retail Food Regulatory Program Standards."

The Program Standards were developed to address the need for national uniformity among retail food regulatory programs, to promote uniform application of the FDA Food Code, and to reduce the occurrence of foodborne illness risk factors. The Program Standards were developed with extensive input from state, tribal, and local regulatory authorities and are intended to help those authorities design and manage a retail food regulatory program that is focused on the reduction of foodborne illness risk factors. They are intended to capture the best management practices currently in use by state, tribal, and local regulatory authorities. The Program Standards initiative represents a comprehensive strategic approach that will help ensure the safety and security of the food supply at the retail level.

FDA requests OMB approval of information collection provisions of the Voluntary National Retail Food Regulatory Program Standards, available at http://www.cfsan.fda.gov/~dms/ret4toc.html .

2. Purpose and Use of the Information Collection

This is a new collection of information. Respondents are State, local, and tribal regulatory agencies that enroll in the Program Standards and seek listing in the FDA National Registry.

The Program Standards define nine essential elements of an effective regulatory program for retail food establishments, establish basic quality control criteria for each element, and provide a means of recognition for those state, local, and tribal regulatory programs that meet the Program Standards. The program elements addressed by the Program Standards are as follows: (1) Regulatory foundation, (2) trained regulatory staff, (3) inspection program based on Hazard Analysis and Critical Control Point (HACCP) principles, (4) uniform inspection program, (5) foodborne illness and food defense preparedness and response, (6) compliance and enforcement, (7) industry and community relations, (8) program support and resources, and (9) program assessment. Each standard includes a list of records needed to document compliance with the standard (referred to in the Program Standards document as "quality records") and has one or more corresponding appendices that contain forms and worksheets to facilitate the collection of information needed to assess the retail food regulatory program against that standard. The respondents are state, local and tribal government agencies. Regulatory agencies may use existing, available records or may choose to develop and use alternate forms and worksheets that capture the same information.

In the course of their normal activities, state, local, and tribal regulatory agencies already collect and keep on file many of the records needed as quality records to document compliance with each of the Program Standards. Although the detail and format in which this information is collected and recorded may vary by jurisdiction, records that are kept as a usual and customary part of normal agency activities include inspection records, written quality assurance procedures and records of quality assurance checks, staff training certificates and other training records, a log or database of food-related illness or injury complaints, records of investigations resulting from such complaints, an inventory of inspection equipment, records of outside audits, and records of outreach efforts (e.g., meeting agendas and minutes, documentation of food safety education activities). No new recordkeeping burden is associated with these existing records, which are already a part of usual and customary program recordkeeping activities by state, local, and tribal regulatory agencies, and which can serve as quality records under the Program Standards.

State, local, and tribal regulatory agencies that enroll in the Program Standards and seek listing in the FDA National Registry are required to report to FDA on the completion of the following three management tasks outlined in the Program Standards: (1) Conducting a program self assessment; (2) conducting a baseline survey of the regulated industry; and (3) obtaining an independent outside audit (verification audit). All three tasks must initially be completed within a 3-year time span. The results are reported to FDA on Form FDA 3519, "FDA National Registry Report" and Form FDA 3520, "Permission to Publish in National Registry." These forms are located in Appendix I of the Program Standards document. If a regulatory agency follows all the recordkeeping recommendations in the individual standards and their appendices, it will have all the information needed to complete the forms. The time required to complete the forms is minimal.

3. Use of Improved Information Technology and Burden Reduction

The respondents submit their information to FDA on Form FDA 3519, "FDA National Registry

Report," and Form FDA 3520, "Permission to Publish in National Registry," both of which are available electronically online and on CD for download.

4. Efforts to Identify Duplication and Use 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. Impact on Small Businesses or Other Small Entities

Respondents are State, local, and tribal regulatory agencies. No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

Although the collection of information related to the Program Standards is voluntary, if information is not collected, regulators may not be employing all the tools necessary to achieve more effective control of foodborne illness risk factors.

The information allows FDA to assist regulatory programs to improve the services they provide to consumers and their regulated industries through the use of the continuous improvement model specified in the Program Standards.

FDA is fully committed to devoting resources to support and encourage the enrolled jurisdictions as they strive to be their best at protecting public health. Jurisdiction enrollment in the Program Standards is necessary to achieve the goal of enrolling 15% (450) of the eligible jurisdictions (3000) in the Program Standards by October 1, 2010; and having at least 50% of the enrolled jurisdictions each meet 25% of the Standards as verified by an audit by October 1, 2010.

If regulators of retail food and foodservice establishments do not focus their efforts on integrating methods to properly identify, assess, and control foodborne illness risk factors, FDA's established goal of a 25% reduction in the occurrence of CDC-identified foodborne illness risk factors by October 1, 2010 would be impossible to achieve.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The information collection provisions of the Program Standards do not involve more than quarterly submission of information to the agency, written responses to the agency in less than 30 days, submission of more than an original and 2 copies, retention of records for more than three years, the use of statistical methods, pledges of confidentiality by FDA not supported by authority established in statute or regulation, or require the disclosure of trade secrets or other confidential information. The collection fully complies with 5 CFR 1320.5(d)(2).

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), in the Federal Register of November 14, 2006 (71 FR 66336), 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. FDA has received comments from the Conference for Food Protection (CFP). In 2006, CFP endorsed the Program Standards with minor changes. Those comments have been incorporated into the Program Standards, 2007 version. The CFP is composed of regulators, industry, academia, professional organizations, and consumers whose purpose is to identify problems, formulate recommendations, and develop and implement practices that relate to food safety.

9. Explanation of Any Payment or Gift to Respondents

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

10. Assurance of Confidentiality Provided to Respondents

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. Justification for Sensitive Questions

This information collection does not involve questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Description of Respondents: Respondents are State, local, and tribal regulatory agencies that enroll in the Program Standards and seek listing in the FDA National Registry.

Recordkeeping

FDA's recordkeeping burden estimate includes time required for a state, local, or tribal agency to review the instructions in the Program Standards, compile information from existing sources, and create any records recommended in the Program Standards that are not already kept in the normal course of the agency's usual and customary activities. Worksheets (Appendices) are provided to assist in this compilation. In estimating the time needed for the program self-assessment (Program Standards 1-8, shown in chart 1 of this document), FDA considered responses from four state and three local jurisdictions that participated in an FDA Program Standards Pilot study. Chart 2 of this document shows the estimated recordkeeping burden for the completion of the baseline data collection and chart 3 of this document shows the estimated recordkeeping burden for the verification audit. The overall program improvement cycle is a 3-year period for completion of all three management tasks.

CHART 1. YEAR ONE – SELF ASSESSMENT

Standard	Recordkeeping Activity	Hours per Recordkeeper (Year One)
NO.1 Regulatory Foundation	Self Assessment: (Appendix A) Completion of worksheet recording results of evaluations and comparison on worksheets.*	16
NO. 2 Trained Regulatory Staff	Self Assessment: (Appendix B-2 and B-4)* Completion of ATN Field Training Worksheet and Documentation of Successful Completion – Field Training Process; completion of summary worksheet of each employee training records.**	19.3
NO. 3 HACCP Principles	Self Assessment: (Appendix C*) Completion of worksheet documentation.	4
NO. 4 Uniform Inspection Program	Self Assessment: (Appendix D*) Completion of worksheet documentation of jurisdiction's quality assurance procedures**	19
NO. 5 Foodborne Illness Investigation	Self Assessment: (Appendix E*) Completion of worksheet documentation.	5
NO. 6 Compliance Enforcement	Self Assessment: (Appendix F*) Selection and review of 20 to 70 establishment files @ 25 minutes per file. Estimate is based on a mean number of 45. Completion of worksheet.	19
NO. 7 Industry &Community Relations	Self Assessment: (Appendix G*) Completion of worksheet.	2
NO. 8 Program Support and Resources	Self Assessment: (Appendix H*) Selection and review of establishment files	8
SUBTOTAL		92.3 HOURS

*Or comparable documentation
** Estimates will vary depending on number of regulated food establishments and the number of inspectors employed by the jurisdiction.

CHART 2. YEAR TWO – BASELINE DATA COLLECTION

Standard	Recordkeeping Activity	Hours Per Recordkeeper (Year Two)
NO. 9 Program Assessment	Baseline Data Collection (Appendices I & J) Selection and inspection of randomly selected statistical sample of 9 to 87 establishments from each of 9 facility types. **	333

** Calculation based on mean sample size of 39 and average FDA inspection time for each establishment type. Estimates will vary depending on number of regulated food establishments within a jurisdiction and the number of inspectors employed by the jurisdiction.

CHART 3. YEAR THREE - VERIFICATION AUDIT

Standard	Recordkeeping Activity	Hours per Recordkeeper (Year Three)
9	Verification Audit (Appendices I & J)**	46.15

** We estimate that no more than 50% of time spent to complete self assessment of all 9 Standards is spent completing verification audit worksheets. Time will be considerably less if less than 9 standards require verification audits.

FDA estimated the annual hours per recordkeeper (i.e., per enrolled jurisdiction) in table 1 of this document by adding the recordkeeping estimates for the management tasks of self assessment, baseline data collection, and verification audit (charts 1, 2, and 3 of this document) that enrolled jurisdictions must perform during a 3-year cycle (92.3 + 333 + 46.15 = 471.45, then dividing the total by three to obtain an annual average (471.15 / 3 = 157.1). The estimates in tables 1 and 2 of this document are based on the estimated participation of 500 regulatory jurisdictions in the Program Standards. . Table 1 shows an increase of 50 hours in the overall recordkeeping burden estimate based on a 0.1 increase in the estimate of annual hours per recordkeeper in the 2007 document. There are approximately 3,000 jurisdictions in the United States and its territories that have retail food regulatory programs. Enrollment in the Program Standards is voluntary, and therefore FDA does not expect all jurisdictions to participate in the near future. In its 2002 operational plan, the FDA National Retail Food Team established a goal of enrolling 15 percent of eligible agencies, or 450 programs, in the Program Standards by the year 2010. For purposes of this burden estimate, it is reasonable to take into account the possibility that this goal could be exceeded by approximately 10 percent, for a total of approximately 500 participating agencies.

Thus, FDA estimates the recordkeeping burden for this collection of information as follows:

Table 1. Estimated Annual Recordkeeping Burden[1]

FDA Worksheets[2]	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Annual Hours per Recordkeeper	Total Hours
Appendices A-J	500	1	500	157.1	78,550
Total Burden Hours					78,550

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

[2] Or comparable documentation.

Reporting

Based on the number and nature of the items that need to be completed, FDA estimates a total of 12 minutes annually for each enrolled jurisdiction to complete both FDA Form 3519, "FDA National Registry Report," and Form 3520, "Permission to Publish in National Registry." Form 3519 requires the name and address of the jurisdiction; completion dates for the self assessment, baseline survey (original and update), and verification audit; names of the person(s) who completed the self-assessment, verification audit, baseline survey, baseline survey update, and action plan; signature of the program manager; and date the form was completed. Form 3520 requires the name of the jurisdiction, completion date of the self assessment, date of the verification audit report, name of the auditor, signature and title of the official completing the form, and date the form was completed.

FDA has added a line and 150 hours to table 2, due to the changes to the Program Standards approved by the Conference for Food Protection. Based on the 2 forms required for the ATN, the nature of the items that need to be completed, and the number of new hires, FDA estimates a total of 150 hours annually for completion of the completion ATN Field Training Worksheet and Documentation of Successful Completion – Field Training Process; (500 jurisdictions with 3 new hires per year at 6 minutes for completion of all forms equals 150 hours per year for completion of both Summary forms). As explained previously in this document, FDA estimates that 500 regulatory jurisdictions will enroll in the Program Standards. The reporting burden in table 2 of this document includes only the time necessary to fill out and send the forms, as compiling the underlying information (including self-assessment reports, baseline surveys, outside audits, and supporting documentation) is accounted for under the recordkeeping estimates in table 1 of this document.

Thus, FDA estimates the reporting burden for this collection of information as follows:

Table 2. Estimated Annual Reporting Burden[b]

FDA Forms*	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3519	500	1	500	6 min	50 hours
3520	500	1	500	6min	50 hours
Retail Food, Restaurant, and Institutional Foodservice – FSIO, ***Documentation of Successful Completion***	500	3	1,500	6 min	150 hours

Total Burden Hours					250 hours

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

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 $2,356,500. (78,550 burden hours X $30/hr = $2,356,500).

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

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

14. Annualized Cost to 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. Explanation for Program Changes or Adjustments

This is a new collection of information. The new burden hours are caused when State, local, and tribal regulatory agencies voluntarily enroll in the Program Standards and seek listing in the FDA National Registry. The regulatory agencies follow recordkeeping recommendations and report to FDA on the completion of the three management tasks outlined in the Program Standards.

16. Plans for Tabulation and Publication and Project Time Schedule

The agency lists regulatory agencies that have enrolled in the Draft Voluntary National Retail Food Regulatory Program Standards on the web and updates the list quarterly, including the enrolled jurisdictions' contact information, enrollment dates, and self-reported and verified status of each of the program standards.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

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

No exceptions to the certification statement were identified.