Voluntary National Retail Food Regulatory Program Standards

OMB Control No. 0910-0621

SUPPORTING STATEMENT, Part A

Terms of Clearance: None.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

While the responsibility for regulating retail and food service establishments lies primarily with state, local, territorial 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 FD&C 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 FD&C 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 major contributing factors associated with foodborne illness outbreaks. Five of these contributing factors directly relate to retail and food service establishments and are called "foodborne illness risk factors" by FDA. In an effort to assist state, local, territorial, and tribal regulators, as well as 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). 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 federal, state, and local regulatory authorities, industry, trade and professional associations, academia, and consumers. They are intended to help authorities responsible for the regulation of food at the retail level to design and manage a food safety program focused on the reduction of foodborne illness risk factors, and to capture best management practices currently in use by regulatory authorities.

FDA requests OMB approval of information collection provisions of the Program Standards and the draft 2013 revision, which is available at: http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/ucm245409.htm, as well as Form FDA 3519, "FDA National Registry Report" and Form FDA 3520, "Permission to Publish in National Registry."

2. Purpose and Use of the Information Collection

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 federal, state, local, territorial 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 conformance with the standard (referred to in the Program Standards document as "quality records") and has one or more corresponding forms and worksheets to facilitate the collection of information needed to assess the retail food regulatory program against that standard. The respondents are federal, state, local, territorial, 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, federal, state, local, territorial, and tribal regulatory agencies already collect and keep on file many of the records needed as quality records to document conformance 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 federal, state, local, territorial, and tribal regulatory agencies, and which can serve as quality records under the Program Standards.

Federal, state, local, territorial, and tribal regulatory agencies that enroll in the Program Standards and seek listing in the FDA National Registry must 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 risk factor study of the regulated industry, and (3) obtaining an independent outside audit (verification audit). 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 the Program Standards document. If a regulatory agency follows all the recordkeeping recommendations in the individual standards and their corresponding worksheets, it will have all the information needed to complete the forms.

In April 2012, the Conference for Food Protection recommended that FDA make two changes to the Program Standards. The changes have been incorporated into the 2013 version, the draft of which is available at: http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/ucm245409.htm. The first change was the addition of a new criterion in Standard 9, Program Assessment. In order to show conformance with Standard 9, jurisdictions must implement an intervention strategy to address risk factors identified in the risk factor study, and then assess the effectiveness of the intervention strategy through subsequent risk factor studies or other similar tools. In the course of their normal activities, state, local, tribal, territorial and Federal regulatory

agencies already implement and document intervention strategies to address identified risk factors at regulated food establishments. The intention of the new criterion in Standard 9 is two-fold: (1) To ensure that development and implementation of the intervention strategy is guided by data collected through the risk factor study, or other similar tools; and (2) To ensure that the regulatory agency considers the effectiveness of the implemented intervention strategy in light of subsequent data. Accordingly, we have not modified our estimate that the recordkeeping associated with Standard 9 will take 333 hours, as shown in Table 2. The second change was the creation of an Administrative Procedures document. Stakeholders requested that information pertaining to enrollment and participation in the Program Standards be included in a separate, stand-alone document. Therefore, the information about the administration of the Program Standards, previously in Standard 9, is now provided in the Administrative Procedures document. This change did not require us to modify our burden estimates.

Description of Respondents: The respondents are federal, state, local, territorial, and tribal regulatory agencies that enroll in the Program Standards and seek listing in the FDA National Registry.

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. The agency estimates that about twenty-five percent (25%) of the submissions will be submitted electronically in the next three years.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is unaware of any comprehensive inventory of Program Standard enrollment 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

FDA estimates that none of the respondents are small businesses. Respondents are federal, state, local, territorial, and tribal regulatory agencies. No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally, i.e., upon enrollment in the Program Standards and within a 12 month to 60 month period thereafter. 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.

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

There are no special circumstances associated with this collection of 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), in the Federal Register of February 3, 2014 (79 FR 6200), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA did not receive any comments in response to the notice.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payments or gifts to respondents.

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 that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

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

12 a. Annualized Hour Burden Estimate

As noted in Section 2 above, in April 2012, the Conference for Food Protection recommended that FDA make two changes to the Program Standards. The changes have been incorporated into the 2013 version, the draft of which is available on FDA's website. The first change was the addition of a new criterion in Standard 9. In order to show conformance with Standard 9, jurisdictions must implement an intervention strategy to address risk factors identified in the risk factor study, and then assess the effectiveness of the intervention strategy through subsequent risk factor studies or other similar tools. The second change was the creation of an Administrative Procedures document. The procedures for enrolling and participating in the Program Standards were previously included in Standard 9, along with other criteria specific to conducting a risk factor study. Stakeholders requested that information pertaining to enrollment and participation in the Program Standards be included in a separate, stand-alone document. Therefore, the information about the administration of the Program Standards, previously in Standard 9, is now provided in the Administrative Procedures document.

FDA analyzed whether incorporation of these two changes alters its estimate of the

recordkeeping and reporting burdens. FDA concluded that there will be no change to the annual recordkeeping burden estimate. In the course of their normal activities, state, local, territorial, tribal and Federal regulatory agencies already implement and document intervention strategies to address identified risk factors at regulated food establishments. The intention of the new criterion in Standard 9 is two-fold: (1) to ensure that development and implementation of the intervention strategy is guided by data collected through the risk factor study, or other similar tools; and (2) to ensure that the regulatory agency considers the effectiveness of the implemented intervention strategy in light of subsequent data. FDA notes that jurisdictions have the option to analyze their inspection data, as indicated by the Standard 9 criteria, in lieu of conducting a risk factor study. This is a less resource-intensive method for tracking risk factor trends over time. However, the agency has not changed its estimate of 333 hours for Standard 9 shown in Table 2 of this document. The agency will reevaluate its estimate based on data it receives in the future from participating jurisdictions. As stated in the preceding paragraph, the second change resulted in the relocation of existing information from Standard 9 to the Administrative Procedures document in the 2013 version of the Program Standards. Because there were no changes to content, there will be no changes to the annual recordkeeping burden. The two noted changes had no effect on the reporting burden hour estimates shown in Table 2 of this document.

Recordkeeping

FDA's recordkeeping burden estimate includes time required for a federal, state, local, territorial 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 are provided to assist in this compilation. In estimating the time needed for the program self-assessment (Program Standards 1 through 8, shown in Table 1 of this document), FDA considered responses from four state and three local jurisdictions that participated in a FDA Program Standards Pilot study. Table 2 of this document shows the estimated recordkeeping burden for the completion of the risk factor study data collection and Table 3 of this document shows the estimated recordkeeping burden for the verification audit.

Table 1.—Self-Assessment

Standard	Recordkeeping Activity	Hours per Record
No. 1: Regulatory Foundation	Self-Assessment: Completion of worksheet recording results of evaluations and comparison on worksheets[1]	16
No. 2: Trained Regulatory Staff	Self-Assessment: Completion of CFP Field Training Manual and Documentation of Successful Completion--Field Training Process; completion of summary worksheet of each employee training records[1, 2]	19.3
No. 3: HACCP Principles	Self-Assessment: Completion of worksheet documentation[1]	4
No. 4: Uniform Inspection Program	Self-Assessment: Completion of worksheet documentation of jurisdiction's quality assurance procedures [1, 2]	19
No. 5: Foodborne Illness Investigation	Self-Assessment: Completion of worksheet documentation[1]	5

No. 6: Compliance Enforcement	Self-Assessment: 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[1]	19
No. 7: Industry & Community Relations	Self-Assessment: Completion of worksheet[1]	2
No. 8: Program Support and Resources	Self-Assessment: Selection and review of establishment files [1]	8
Total		92.3

[1] Or comparable documentation.

[2] Estimates will vary depending on number of regulated food establishments and the number of inspectors employed by the jurisdiction.

Table 2. – Risk Factor Study Data Collection

Standard	Recordkeeping Activity	Hours Per Record
No. 9: Program Assessment	Risk Factor Study and Intervention Strategy[1]	333

[1] 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.

Table 3.—Verification Audit

Activity	Recordkeeping Activity	Hours per Record
Administrative Procedures	Verification Audit[1]	46.15

[1] 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 estimates the burden of this collection of information as follows:

Table 4.—Estimated Annual Recordkeeping Burden[1]

Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Recordkeeping for FDA Worksheets[2]	500	1	500	94.29	47,145

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

[2] Or comparable documentation.

FDA bases its estimates of the number of recordkeepers and the hours per record on its experience with the Program Standards over the past 14 years. As of April 15, 2014, 588 jurisdictions were enrolled in the Program Standards. However, based upon the level of ongoing support provided by FDA to enrolled jurisdictions and the number of forms submitted annually, FDA estimates that no more than 500 jurisdictions actively participate in the Program Standards during any given year. 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.

FDA bases its estimate of the hours per record on the recordkeeping estimates for the

management tasks of self-assessment, risk factor study, and verification audit (Tables 1, 2, and 3 of this document) that enrolled jurisdictions must perform a total of 471.45 hours (92.3 + 333 + 46.15 = 471.45). Enrolled jurisdictions must conduct the work described in Tables 1, 2, and 3 over a five year period. Therefore FDA estimates that, annually, 500 recordkeepers will spend 94.29 hours (471.45/5 = 94.29) performing the required recordkeeping for a total of 47,145 hours as shown in Table 4 of this document.

Reporting

FDA requires regulatory jurisdictions that participate in the Program Standards to submit two forms annually: Form FDA 3519, "FDA National Registry Report," and Form FDA 3520, "Permission to Publish in National Registry." Form FDA 3519 requires the name and address of the jurisdiction; completion dates for the self-assessment, risk factor study (original and update), and verification audit; names of the person(s) who completed the self-assessment, verification audit, risk factor study (baseline report), risk factor study (update), and action plan; signature of the program manager; and date the form was completed. Form FDA 3520 requires the name and address of the jurisdiction, contact information for the enrollee's designated contact person, completion date of the self-assessment, date of the verification audit report, name of the auditor, signature of the official completing the form, and date the form was completed.

The reporting burden in Table 5 of this document includes only the time necessary to fill out and send the forms, as compiling the underlying information (including self-assessment reports, Risk Factor Study data collection, outside audits, and supporting documentation) is accounted for under the recordkeeping estimates in Table 4 of this document.

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

Table 5.--Estimated Annual Reporting Burden[1]

Activity	FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Submission of "FDA National Registry Report"	3519	500	1	500	0.1	50
Submission of "Permission to Publish in National Registry"	3520	500	1	500	0.1	50
Request for documentation of successful completion of staff training	Conference for Food Protection Training Plan and Log	500	3	1,500	0.1	150
Total						250

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

FDA bases its estimates of the number of respondents and the hours per response on its experience with the Program Standards over the past 14 years. As explained previously in this document, FDA estimates that no more than 500 regulatory jurisdictions will participate in the

Program Standards in any given year. FDA estimates a total of 12 minutes annually for each enrolled jurisdiction to complete both forms. FDA bases its estimate on the small number of data elements on the two forms and the ease of availability of the information. FDA estimates that, annually, 500 regulatory jurisdictions will submit one Form FDA 3519 for a total of 500 annual responses. Each submission is estimated to take 0.1 hour per response for a total of 50 hours. FDA estimates that, annually, 500 regulatory jurisdictions will submit one Form FDA 3520 for a total of 500 annual responses. Each of these submissions is estimated to take 0.1 hour per response for a total of 50 hours. FDA estimates that, annually, 500 regulatory jurisdictions will submit three requests for documentation of successful completion of staff training using the CFP Training Plan and Log for a total of 1,500 annual responses. Each submission is estimated to take 0.1 hour per response for a total of 150 hours. Thus, the total reporting burden for this information collection is 250 hours.

12 b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is approximately $1,443,651.70 per year. FDA estimates that the average hourly wage for the employees engaging in recordkeeping and submitting information to FDA would be equivalent to a GS-4/Step-2 level in the locality pay area of Washington-Baltimore in 2014, approximately $15.23 per hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $30.46/hour. Thus, the overall estimated cost incurred by the respondents is $1,443,651.70. (47,395 burden hours x $30.46/hr = $1,443,651.70).

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

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

At the agency, professional employees collect, review, and maintain the Program Standards submissions, which requires about 260 hours annually. FDA estimates that, on average, the hourly cost for review and evaluation of the submissions is approximately $43.09 per hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2014. To account for overhead, this cost is increased by 100 percent, making the total cost $86.18 per hour. Thus, FDA estimates the annual cost to the Federal government to be $22,406.80 ($86.18/hour x 260 hours).

15. Explanation for Program Changes or Adjustments

There was no change in the burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA lists regulatory agencies that have enrolled in the 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

There are no exceptions to the certification.