FOOD AND DRUG ADMINISTRATION
Voluntary National Retail Food Regulatory Program Standards

OMB Control No. 0910-0621

SUPPORTING STATEMENT

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 1003(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 1003(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.

In conjunction with the Program Standards FDA has developed Form FDA 3958. The form consolidates FDA Forms 3519 and 3520 and we believe reduces burden on respondents. Accordingly, we request OMB approval of the information collection provisions of the Program Standards (available at: http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/ucm245409.htm), and Form FDA 3958, "*Voluntary National Retail Food Regulatory Program Standards FDA National Registry Report*."

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 will be reported to FDA on Form FDA 3958, "*Voluntary National Retail Food Regulatory Program Standards FDA National Registry Report*."

In April 2016, the Conference for Food Protection (CFP) recommended that FDA make a change in Program Standard #4 – Uniform Inspection Program, more specifically to change Program Standard #4's Program Self-Assessment and Verification Audit Form. Once changes have been incorporated into the 2017 version, it will be available on FDA's website.

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

Respondents submit information to FDA on consolidated Form FDA 3958, "*FDA National Registry Report*," available electronically. Form FDA 3958 is fillable, fileable, and signable. The agency estimates that about fifty percent (50%) of the submissions will be submitted electronically.

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.

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 March 20, 2017 (82 FR 14369), we published a 60 day notice requesting public comment on the proposed collection of information. FDA received four comments, two of them duplicative. One PRA-related comment noted that standards certification should last for seven years. We appreciate this comment, however we believe that the current practice best ensures the quality of public health service to stakeholders. Two comments supported the information collection.

9. Explanation of Any Payment or Gift to Respondents

No gifts or payments are provided 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

12a. *Annualized Hour Burden Estimate*

Recordkeeping

We base our estimate of the number of recordkeepers and the hours per record on our experience with the Program Standards over the past 16 years. As of September 30, 2016, 711 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. Enrolled jurisdictions must conduct the work described in Tables 1, 2, and 3 below over a five year period:

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

Standard	Recordkeeping Activity	Hours per Record
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.

Our recordkeeping estimate, therefore, is 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.

Reporting

In the past, FDA required regulatory jurisdictions that participated 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*." FDA has now created a new consolidated FDA Form 3958 "*Voluntary National Retail Food Regulatory Program Standards FDA National Registry Report*" that has four parts: Part 1 requires the name and address of the jurisdiction; name and contact information for the contact person for this jurisdiction; the jurisdictions website address and if the jurisdiction is willing to serve as an auditor for another jurisdiction. Part 2 requires information about enrollment, whether this jurisdiction is a new enrollee and the date of enrollment; indication whether this jurisdiction would like to be removed

from the jurisdiction listing; indication of updated findings to the self-assessment or verification audit. Part 3 requires information about self-assessment findings and verification audit findings; dates when self-assessment was completed; which standards have been met as determined by the self-assessment; which standards have been met as verified by a verification audit including the completion dates. Part 4 requires permission to publish information on FDA's website by checking the appropriate box(es) to indicate what information FDA may publish on the website.

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

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Submission of "Voluntary National Retail Food Regulatory Program Standards FDA National Registry Report"	500	1	500	0.1 (6 minutes)	50
Request for documentation of successful completion of staff training	500	3	1,500	0.1 (6 minutes)	150
TOTAL					200

[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 16 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 6 minutes annually for each enrolled jurisdiction to complete the form. FDA bases its estimate on the small number of data elements on the consolidated form and the ease of availability of the information. FDA estimates that, annually, 500 regulatory jurisdictions will submit one Form FDA 3958 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 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 200 hours.

12b. *Annualized Cost Burden Estimate.*

The annual hour cost burden to respondents is approximately $1,520,721.40 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 2017, approximately $16.06 per hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $32.12/hour. Thus, the overall estimated cost incurred by the respondents is $1,520,721.40. (47,345 burden hours x $32.12/hr = $1,520,721.40).

Type of	Total Burden	Hourly Wage Rate	Total Respondent

Respondent	Hours		Costs
Clerk/Assistant	47,345	$32.12	$1,520,721

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 $45.42 per hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2017. To account for overhead, this cost is increased by 100 percent, making the total cost $90.84 per hour. Thus, FDA estimates the annual cost to the Federal government to be $23,618.40 ($90.84/hour x 260 hours).

15. Explanation for Program Changes or Adjustments

The information collection reflects adjustments. As previously discussed, we estimate the consolidation of Forms FDA 3519 and 3520 into new Form FDA 3958 has resulted in a reduction of 50 burden hours, with a corresponding reduction in annual responses of 500.

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

Display of OMB Expiration Date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.