UNITED STATES FOOD AND DRUG ADMINISTRATION

Voluntary National Retail Food Regulatory Program Standards

OMB Control No. 0910-0621

SUPPORTING STATEMENT **Part A – Justification**:

1. Circumstances Making the Collection of Information Necessary

This information collection request supports Food and Drug Administration's ("FDA" or "we") Voluntary National Retail Food Regulatory Standards Program. While the responsibility for regulating retail and food service establishments lies primarily with State, local, territorial and tribal jurisdictions, we provide 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 (CDC) 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, we have 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.

To assist respondents with the information collection, we developed Form FDA 3958 entitled, "*Voluntary National Retail Food Regulatory Program Standards FDA National Registry Report*." Form FDA 3958 collects information about jurisdiction participation in the program and may be completed electronically at: www.fda.gov/RetailProgramStandards.

We therefore request extension of OMB approval of information collection provisions of the Program Standards which are available at: http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/ucm245409.htm, as well as Form FDA 3958.

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*."

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 3958, "*FDA National Registry Report*," which is available online. The agency estimates that about fifty percent (50%) of the submissions are submitted electronically.

4. Efforts to Identify Duplication and Use of Similar Information

We are 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, we believe there is no duplicative collection of information.

5. Impact on Small Businesses or Other Small Entities

We estimate that none of the respondents are small businesses. Respondents are Federal, State, local, territorial, and tribal regulatory agencies. No small businesses are 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- 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), we published a 60-day notice for public comment in the *Federal Register* on February 21, 2020 (85 FR 10172). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

We do not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted with our Privacy Office to ensure appropriate handling of information collected. This information collection does not request any or trade secret or commercial confidential information. The information to be provided is public in nature. Thus, FDA provides no assurances of confidentiality.

Privacy Act

This information collection request (ICR) is collecting personally identifiable information (PII) or other data of a personal nature. PII is collected in the context of the individuals' professional capacity. Information is collected via Form FDA 3958 (Voluntary National Retail Food Regulatory Program Standards FDA National Registry Report). The PII collected is name, address, telephone number and email address. Although PII is collected, the information collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to routinely retrieve records from the information collected.

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 Cost

12a. Annualized Hour Burden Estimate

Our recordkeeping 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), we 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.

Table 4.--Estimated Annual Recordkeeping Burden

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.

We base our estimates of the number of recordkeepers and the hours per record on our experience with the Program Standards over the past 16 years. Based upon the level of ongoing support provided by FDA to enrolled jurisdictions and the number of forms submitted annually, we estimate 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, we do not expect all jurisdictions to participate.

We base our 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, we estimate that, annually, 500 recordkeepers 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.

Regulatory jurisdictions that participates in the Program Standards submits Form FDA 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 Web site by checking the appropriate box(es) to indicate what information we may publish on the website.

The reporting burden in Table 5 of this document includes 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.

We estimate 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 "*Voluntary National Retail Food Regulatory Program Standards FDA National Registry Report*"	3958	500	1	500	0.1 (6 minutes)	50
Request for documentation of successful completion of staff training	Conference for Food Protection Training Plan and Log	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.

We base our estimates of the number of respondents and the hours per response on our experience with the Program Standards over the past 16 years. As explained previously in this document, we estimate that no more than 500 regulatory jurisdictions will participate in the Program Standards in any given year. We estimate a total of 6 minutes annually for each enrolled jurisdiction to complete the form. We base our estimate on the small number of data elements on the form and the ease of availability of the information. We estimate 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. We estimate 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 $1,646,659.10 per year. We estimate 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 2020, approximately $17.39 per hour. Doubling this wage to account for overhead costs, we estimate the average hourly cost to respondents to be $34.78/hour. Thus, the overall estimated cost incurred by the respondents is $1,646,659.10. (47,345 burden hours x $34.78/hr = $1,646,659.10).

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Clerk/Assistant	47,345	$34.78	$1,646,659

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or 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. We estimate that, on average, the hourly cost for review and evaluation of the submissions is approximately $49.19 per hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2020. To account for overhead, this cost is increased by 100 percent, making the total cost $98.38 per hour. Thus, we estimate the annual cost to the Federal government to be $25,578.80 ($98.38/hour x 260 hours).

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

We list regulatory agencies that have enrolled in the Voluntary National Retail Food Regulatory Program Standards on the web and update 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.