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 helps support implementation of FDA's Voluntary National Retail Food Regulatory Program Standards (the Retail Program Standards). Regulatory Program Standards play a critical role in an integrated food safety system and serve as the foundation for mutual reliance between FDA and other regulatory agencies that work to ensure food safety. The Retail Program Standards define what constitutes a highly effective and responsive program for the regulation of foodservice and retail food establishments. The Retail Program Standards are intended to provide a foundation upon which continuous improvements can be made with the ultimate goal to reduce the occurrence of factors that cause and contribute to foodborne illness. In support of this goal, FDA works cooperatively with our State, local, territorial, and tribal partners using a risk-based approach to leverage limited resources. We engage in education and outreach efforts to facilitate collaboration with our partners in food safety. The Retail Program Standards represent an important component of a comprehensive strategic approach to help ensure the safety and security of the food supply at the retail level. 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 Retail Program Standards were revised most recently in November 2024 and include the following elements: (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. These elements are enumerated and discussed on our website at https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2024 along with worksheets and assessments that allow FDA to determine conformance with the Retail Program Standards. State, local, territorial, tribal, and Federal regulatory agencies that participate in the voluntary program are required to report information demonstrating that a program self-assessment, a risk factor study of the regulated industry, and an independent outside audit (verification audit) have been completed. The information also includes Form FDA 3958, "Voluntary National Retail Food Regulatory Program Standards FDA National Registry Report," which may be completed electronically at https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2024.

We have created a dedicated email at HFP-OIFSSP-ORFP-Leadership-Team@fda.hhs.gov to receive requests for program documentation and the following instruments to support the standardization of food safety inspection officer candidates:

- Form FDA 5017, "Standardized Retail Food Safety Inspection Officer Waiver of Annual Maintenance Requirement," pertains to requests for waivers from maintenance requirements, referenced in section 3-403 of the "FDA Procedures for Standardization of Retail Food Safety Inspection Officers." FDA uses the information submitted on Form FDA 5017 to determine a retail food safety inspection officer's eligibility for re-standardization.

- Form FDA 5018, "Standardized Retail Food Safety Inspection Officer Annual Maintenance Form," captures information verifying that a retail food safety inspection officer has met program standardization requirements in accordance with section 3-403 of the "FDA Procedures for Standardization of Retail Food Safety Inspection Officers."

- Form FDA 5019, "Standardized Retail Food Safety Inspection Officer Nomination Form," collects qualification information from retail food safety inspection officer candidates.

Forms FDA 5017, 5018, and 5019 are completed electronically by respondents and submitted to the appropriate FDA Retail Food Specialist. The Retail Food Specialists assigned by state are found at FDA's Retail Program Standards website: https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/directory-fda-retail-food-specialists.

We therefore request OMB approval of information collections included in our Voluntary National Retail Food Regulatory Program Standards and Forms FDA 3958, 5017, 5018, and 5019 as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

State, local, territorial, tribal, and Federal regulatory agencies that enroll in the program 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 risk factor study of the regulated industry; and (3) obtaining an independent outside audit (verification audit). The results are reported on FDA's website at https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2024. If a regulatory agency follows all the recordkeeping recommendations in the individual standards and their sample worksheets, it will have all the information needed to complete the reports. We use the information to evaluate program effectiveness and to report on participation. The information allows FDA to assist regulatory programs to improve the services they provide to consumers and their regulated industries using the continuous improvement model specified in the Retail Program Standards.

Description of Respondents: The respondents are State, local, territorial, tribal, and Federal regulatory agency officials that participate in FDA's Retail Food Safety Program.

3. Use of Improved Information Technology and Burden Reduction

FDA utilizes automated reporting instruments to collect information from participating respondents. We have created a dedicated e-mailbox at HFP-OIFSSP-ORFP-Leadership-Team@fda.hhs.gov to receive requests for program documentation and have developed the

following instruments to support the standardization of food safety inspection officer candidates. We expect that 100% of the respondents to this collection of information will submit their responses electronically.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

There is no undue impact on small entities.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule occurs occasionally, i.e., upon enrollment in the program and within a 12- to 60-month period thereafter. Although the collection of information related to both the Retail Program Standards and Standardization is voluntary, it serves as an effective tool in protecting against foodborne illness risk factors.

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 July 17, 2026 (91 FR 44857). One comment was received that was generally favorable of the collection of information.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974

In preparing this supporting statement, we consulted with our Privacy Office to ensure appropriate handling of information collected.

This ICR collects personally identifiable information (PII) in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via Forms FDA 3958 (Voluntary National Retail Food Regulatory Program Standards FDA National Registry Report), FDA 5017 (Standardized Retail Food Safety Inspection Officer Waiver of Annual Maintenance Requirement Form), FDA 5018 (Standardized Retail Food Safety Inspection Officer Annual Maintenance Form), and FDA 5019 (Standardized Retail Food Safety Inspection Officer Nomination Form) is employer identification number, payment identification number, name, email address, telephone number, work address, and fax number. Information collected via Forms FDA 3958, 5017, 5018, and 5019 is retrievable by agency or branch office. FDA determined that although PII is collected,

the 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 retrieve records from the information collected. Individuals completing Forms FDA 3958, 5017, 5018, and 5019 will do so via a webpage where a notice is displayed. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

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

We believe that recordkeeping associated with the attendant regulatory activities would be usual and customary business practice for regulating officials. Accordingly, we characterize burden associated with the information collections as reporting burden.

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

Voluntary National Retail Program Standards (November 2024)	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Program self-assessments for element Nos. 1 through 8	500	1	500	92.3	46,150
Program element No. 9; risk factor study and intervention strategy	500	1	500	333	166,500
Program Verification audit	500	1	500	46.15	23,075
Program records; associated documentation/maintenance of worksheets, assessments, associated program tools	500	1	500	94.29	47,145
FDA Form 3958; VNRFP National Registry Report	500	1	500	0.2 (12 minutes)	100
Requests for program documentation (dedicated email)	500	3	1,500	0.1 (6 minutes)	150
Form FDA 5017; Waiver of Annual Maintenance Requirement	10	1	10	0.35 (21 minutes)	4
Form FDA 5018; Retail Food Safety Inspection Officer Annual Maintenance	130	1	130	0.35 (21 minutes)	46

Form FDA 5019; Retail Food Safety Inspection Officer Nomination	14	1	14	0.35 (21 minutes)	5
Total			4154		283,175

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

Our estimate of burden for the associated program activities as identified in Table 1 is based on our experience with the information collection, along with other regulatory standards programs we administer.

12b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is $11,683,800.50 per year. We estimate that the average hourly wage for the employees submitting information to FDA would be equivalent to a GS-4/Step-2 level in the locality pay area of Washington-Baltimore in 2026, approximately $20.63 per hour. Doubling this wage to account for overhead costs, we estimate the average hourly cost to respondents to be $41.26/hour. Thus, the overall estimated cost incurred by the respondents is $11,683,800.50 (283,125 burden hours × $41.26/hr).

Table 2. --Annual Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Clerk/Assistant	283,175	$41.26	$11,683,800.50

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

We assume 260 hours annually to administer the information collection and factor hourly costs for reviewing and evaluating submissions at $58.35 per hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2026. We account for overhead by doubling this figure to $116.70 per hour and calculate total annual costs to the Federal government to be $30,342 ($116.70/hour × 260 hours).

15. Explanation for Program Changes or Adjustments

Although ROCIS reflects an increase in burden, no adjustments have been made to the currently approved burden estimate since the last OMB approval. The estimated annual burden increases by 53 hours due to two corrections. For Form FDA 3958, we corrected the estimated completion time from 6 minutes to 12 minutes to match the time stated on the form, increasing the annual burden from 50 to 100 hours. We also corrected a calculation error in the table for Form FDA 5018, increasing is estimated annual burden from 43 to 46 hours.

Table 4.--Changes or Adjustments to Burden Estimates

Activity/CFR Section	Previously Approved Annual Burden Hours	Requested Annual Burden Hours	Difference (Hours) (+/-)	Rationale for Change (Estimate Revision/Programmatic)
FDA Form 3958; VNRFP National Registry Report)	50	100	+50	The burden to complete an individual Form FDA 3958 was listed as 6 minutes in the burden chart in Item 12a while the burden on the form itself was listed as 12 minutes. We adjusted to match the form in this supporting statement and changed the burden from 6 to 12 minutes, which increased the total burden for completing the form from 50 to 100 hours, or a difference of 50 hours.
Form FDA 5018; Retail Food Safety Inspection Officer Annual Maintenance	43	46	+3	The burden to complete an individual Form FDA 5018 was calculated in error. The revised burden changed from 43 hours to 46 hours, or a difference of 3 hours.
Total	93	146	+53	

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 our webpage at https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/listing-jurisdictions-enrolled-voluntary-national-retail-food-regulatory-program-standards 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

The OMB control number and expiration date will be displayed as required by the PRA.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.