UNITED STATES FOOD & DRUG ADMINISTRATION

Voluntary National Retail Food Regulatory Program Standards

OMB Control No. 0910-0621 - Revision

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 August 2022 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-august-2022> 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-august-2022>.

Finally, we are revising the information collection to include the following forms:

* **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,*” provides verification 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.”
* **Proposed FDA 5019**, “*Standardized Retail Food Safety Inspection Officer Nomination Form*,” allows FDA to collect qualification information from retail food safety inspection officer candidates.

Forms FDA 5017, 5018, and 5019 will be 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 as discussed in this supporting statement.

1. 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 must report information to FDA. 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 through the use of 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.

1. 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 [retailfoodprotectionteam@fda.hhs.gov](mailto:retailfoodprotectionteam@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.

1. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

1. Impact on Small Businesses or Other Small Entities

There is no undue impact on small entities.

1. 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.

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

There are no special circumstances associated with this collection of information.

1. 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 June 30, 2023 (88 FR 43272). No comments were received.

1. Explanation of Any Payment or Gift to Respondents

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

1. 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). PII is collected 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, name, email address, telephone number, work address and fax number. Information collected via **Forms FDA 5017, 5018**, and **5019** is maintained in a Privacy Act system of records as described in Government-wide System of Records Notice (SORN) OPM/GOVT-1 General Personnel Records. (See 80 FR 74815.) Individuals completing Forms FDA 3958, 5017, 5018, and 5019 will do so electronically. 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.

1. Justification for Sensitive Questions

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

1. Estimates of Annualized Burden Hours and Cost

*12a. Annualized Hour Burden Estimate*

We believe that the attendant 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.

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| --- | --- | --- | --- | --- | --- |
| Table 1. --Estimated Annual Reporting Burden1 | | | | | |
| Voluntary National Retail Program Standards (August 2022) | 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 | 0.1  (6 minutes) | 50 |
| Requests for program documentation (dedicated email) | 500 | 3 | 1,500 | 0.1  (6 minutes) | 150 |
| Proposed Form FDA 5017; Waiver of Annual Maintenance Requirement | 10 | 1 | 10 | 0.35  (21 minutes) | 3.5 |
| Proposed Form FDA 5018; Retail Food Safety Inspection Officer Annual Maintenance | 130 | 1 | 130 | 0.35  (21 minutes) | 43 |
| Proposed Form FDA 5019; Retail Food Safety Inspection Officer Nomination | 14 | 1 | 14 | 0.35  (21 minutes) | 5 |
| Total |  |  | 4,154 |  | 283, 121.5 |

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. Upon reorganizing the collection to reflect the cumulative activities, we have accounted for burden that may be attributable recordkeeping for risk-factor studies and verification tasks that may have been previously overlooked. The burden we attribute to completing and submitting Form FDA 3958, “Voluntary National Retail Food Regulatory Program Standards FDA National Registry Report*,*” is exclusive of other program records, which we account for in row 5. We have also accounted for burden we assume will be attendant to the completion and submission of newly developed agency forms. As a result of these changes and adjustments, the information collection reflects an increase of 235,776.5 hours and 1,654 responses annually.

*12b. Annualized Cost Burden Estimate*

The annual hour cost burden to respondents is approximately $10,741,629.71 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 2023, approximately $18.97 per hour. Doubling this wage to account for overhead costs, we estimate the average hourly cost to respondents to be $37.94/hour. Thus, the overall estimated cost incurred by the respondents is $10,741,375.71 (283,121.5 burden hours x $37.94/hr).

Table 2. -- Annual Cost Burden Estimate

|  |  |  |  |
| --- | --- | --- | --- |
| Type of Respondent | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
| Clerk/Assistant | 283,121.5 | $37.94 | $10,741,375.71 |

1. 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.

1. 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 $53.67 per hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2023. We account for overhead by doubling this figure to $107.34 per hour and calculate total annual costs to the Federal government to be $27,908.40 ($107.34/hour x 260 hours).

1. Explanation for Program Changes or Adjustments

We have adjusted our estimated burden to reflect an increase of 235,776.5 hours and 1,654 responses annually, which we attribute to increased participation in the program and the introduction of new collection instruments.

1. 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.

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

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

1. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.