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

Dated: September 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20229 Filed 9–18–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2286]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary National Retail Food Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by October 19, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0621. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Voluntary National Retail Food Regulatory Program Standards

OMB Control Number 0910–0621—Revision

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. Respondents to the information collection are State, local, Territorial, and Tribal governments.

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 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 additional Agency resources. We have created a dedicated emailbox at *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:

- Proposed Form FDA 5017, ''Standardized Retail Food Safety Inspection Officer Waiver of Annual Maintenance Requirement Form,'' 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 food safety inspection officer's eligibility for restandardization.
- Proposed Form FDA 5018, ''Standardized Retail Food Safety Inspection Officer Annual Maintenance Form,'' provides verification that a 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 Form FDA 5019, ''Standardized Food Safety Inspection Officer Nomination Form,'' allows FDA to collect qualification information from food safety inspection officer candidates.

In the **Federal Register** of August 30, 2023 (88 FR 42372) FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Voluntary national retail program standards (August 2022)	Number of respondents	Number 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; Food Safety Inspection Officer Annual Maintenance.	130	1	130	0.35 (21 minutes).	43
Proposed Form FDA 5019; 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 FDA Form 3958, ''Voluntary National Retail Food Regulatory Program Standards FDA National Registry Report,'' is exclusive of other program records, which we account for in row 4. 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.

Dated: September 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20226 Filed 9–18–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3743]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Records; Electronic Signatures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection applicable to the electronic record signature provisions found in Agency regulations.

DATES: Either electronic or written comments on the collection of information must be submitted by November 20, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 20, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as