their sex assigned at birth on their original birth certificate (male, female, don't know, prefer not to answer). Next, respondents are asked to report their current gender identity (male, female, transgender, I use a different term, prefer not to answer). This two-step series aligns with recommendations from the National Academies of Sciences, Engineering, and Medicine's (NASEM's) recent report, ''Measuring Sex, Gender Identity, and Sexual Orientation.'' These items have also been cognitively tested for inclusion in the Medicare Current Beneficiaries Survey under the MCBS Generic Clearance and performed well.

Estimated Program Burden: ACL estimates the burden associated with this collection of information as follows:

Respondent/data collection activity	Number of respondents (maximum)	Responses per respondent	Hours per response	Annual burden hours
Survey, Stratified Random Sample	5,400	1	5/60	450
Total	5,400	1	5/60	450

Dated: June 19, 2023.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2023–13968 Filed 6–29–23; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2286]

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary National Retail Food Regulatory Program Standards

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with our Voluntary National Retail Food Regulatory Program (VNRFRP) Standards.

DATES: Either electronic or written comments on the collection of information must be submitted by August 29, 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 August 29, 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 well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–2286 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary National Retail Food Regulatory Program Standards.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://*

www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

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: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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 (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 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 re-standardization.
- 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.

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
			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: June 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–13930 Filed 6–29–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–N–1427; FDA–2022–N–0863; FDA–2023–N–0187; FDA–2013–N–1393; FDA–2022–D–0814; FDA–2013–N–0796; FDA–2016–N–0736; and FDA–2019–N–3065]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Hazard Analysis and Critical Control Point (HACCP) Procedures for the Safe and Sanitary Processing and Importing of Juice	0910–0466	4/30/2026
Monthly Monitoring Study	0910–0914	4/30/2026
Premarket Approval of Medical Devices	0910–0231	5/31/2026
Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions	0910–0233	5/31/2026
Infant Formula Requirements	0910–0256	5/31/2026
Testing Communications on Medical Devices and Radiation-Emitting Products	0910–0678	5/31/2026
Tracking Network for PETNet, LivestockNet, and SampleNet	0910–0680	5/31/2026
Required Warnings for Cigarette Packages and Advertisements	0910–0877	5/31/2026