states, territories, and tribes are also required to submit an APSR and a financial report called the CFS–101. The APSR is a yearly report that discusses progress made by a state, territory or tribe in accomplishing the goals and objectives cited in its CFSP (45 CFR 1357.16(a)). The APSR contains new and updated information about service needs and organizational capacities throughout the five-year plan period and, beginning with the submission due on June 30, 2021, will also include information on the use of the Family First Transition Grants and Funding Certainty Grants authorized by the Family First Transition Act included in Public Law (P.L.)116–94. The CFS–101 has three parts. Part I is an annual budget request for the upcoming fiscal year. Part II includes a summary of planned expenditures by program area for the upcoming fiscal year, the estimated number of individuals or families to be served, and the geographical service area. Part III includes actual expenditures by program area, numbers of families and individuals served by program area, and the geographic areas served for the last complete fiscal year. The revisions to the CFS–101 form are to streamline the data entry and to remove from Part III of the CFS–101 requests for prior year estimates on use of funds that are not required by law.

*Respondents:* States, territories, and tribes must complete the CFSP, APSR, and CFS–101. Tribes and territories are exempted from the monthly caseworker visits reporting requirement of the CFSP/APSR. There are approximately 180 tribal entities that currently receive IV–B funding. There are 53 states (including the Commonwealth of Puerto Rico, the District of Columbia, and the Virgin Islands) that must complete the CFSP, APSR, and CFS–101. There are a total of 233 possible respondents.

ANNUAL BURDEN ESTIMATES

| Instrument | Total number of respondents | Total number of responses per respondent | Average burden hours per response | Total burden hours | Annual burden hours |
|---|---|---|---|---|---|
| APSR | 233 | 3 | 82 | 57,318 | 19,106 |
| CFSP | 47 | 1 | 123 | 5,781 | 1,927 |
| CFS–101, Part I, II, and III | 233 | 3 | 5 | 3,495 | 1,165 |
| Caseworker Visits | 53 | 3 | 99.33 | 15,794 | 5,265 |

*Estimated Total Annual Burden Hours:* 27,463.

**Authority:** Title IV–B, subparts 1 and 2 of the Social Security Act (the Act), and title IV–E, section 477 of the Act; sections 106 and 108 of CAPTA (42 U.S.C. 5106a. and 5106d.); and P.L. 116–94, the Family First Transition Act within Section 602, Subtitle F, Title I, Division N of the Further Consolidated Appropriations Act, 2020.

**John M. Sweet Jr,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2020–14881 Filed 7–9–20; 8:45 am]

**BILLING CODE 4184–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0017]**

### 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 August 10, 2020.

**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:** Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *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—Extension*

This information collection request supports implementation of FDA's Voluntary National Retail Food Regulatory Program Standards (the Program Standards). 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 the State, local, territorial, tribal, and Federal regulatory programs that meet the Program Standards. The program elements addressed by the Program Standards are: (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 State, local, territorial, tribal, and potentially other Federal regulatory 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, State, local, territorial, tribal, and Federal regulatory agencies already collect and keep on file many of the records needed as quality records to document compliance 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, 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 State, local, territorial, tribal, and Federal regulatory agencies, and which can serve as quality records under the Program Standards.

State, local, territorial, tribal and Federal regulatory agencies that enroll in the Program Standards 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-2019.* 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.

Recordkeeping

FDA's recordkeeping burden estimate includes time required for a State, local, territorial, tribal, or Federal 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. Sample 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), FDA considered responses from four State and three local jurisdictions that participated in an FDA Program Standards Pilot study. Table 2 shows the estimated recordkeeping burden for the completion of the baseline data collection, and table 3 shows the estimated recordkeeping burden for the verification audit.

In the **Federal Register** of February 21, 2020 (85 FR 10172), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

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 Conference for Food Protection (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 at 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 percent of time spent to complete self-assessment of all nine standards is spent completing verification audit worksheets. Time will be considerably less if less than nine standards require verification audits.

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| Activity | Number of recordkeepers | Number 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.

FDA bases its estimates of the number of recordkeepers and the hours per record on its 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, FDA estimates 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, FDA does not expect all jurisdictions to participate.

FDA bases its 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) 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 5-year period. Therefore, FDA estimates that, annually, 500 recordkeepers will 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.

Reporting

Form FDA 3958, ''Voluntary National Retail Food Regulatory Program Standards FDA National Registry Report,'' used for reporting to FDA, consists of four parts. Part 1 requires the name and address of the jurisdiction; name and contact information for the contact person for this jurisdiction; the jurisdiction's 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; and 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; and 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 website by checking the appropriate box(es) to indicate what information FDA may publish on the website.

The reporting burden in table 5 includes only the time necessary to complete a report, 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.

FDA estimates the reporting burden for this collection of information as follows:

TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Activity | Number of respondents | Number 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''. | 500 | 1 | 500 | 0.1 (6 minutes) | 50 |
| Request for documentation of successful completion of staff training. | 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.

FDA bases its estimates of the number of respondents and the hours per response on its experience with the Program Standards. As explained previously, FDA estimates that no more than 500 regulatory jurisdictions will participate in the Program Standards in any given year. FDA estimates a total of 6 minutes annually for each enrolled jurisdiction to complete the form. FDA bases its estimate on the small number of data elements on the form and the ease of availability of the information. FDA estimates that, annually, 500 regulatory jurisdictions will submit one Form FDA 3598 for a total of 500 annual responses. Each submission is estimated to take 0.1 hour (or 6 minutes) per response for a total of 50 hours. In addition, FDA estimates 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 (or 6 minutes) per response for a total of 150 hours. Thus, the total reporting burden for this information collection is 200 hours.

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: July 6, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020–14879 Filed 7–9–20; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. FDA–2018–N–2434, FDA–2016–N–3535, FDA–2013–N–1619, FDA–2016–N–0736, FDA–2019–N–3885, FDA–2013–N–1423, FDA–2013–N–0804, FDA–2016–N–3995, FDA–2018–D–1592, FDA–2016–N–2066, and FDA–2017–N–0366]**

### 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:** Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *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 |
|---|---|---|
| Formal Meetings Between the Food and Drug Administration and Sponsors and Applicants of Prescription Drug User Fee Act Products | 0910–0429 | 5/31/2023 |
| Special Protocol Assessments | 0910–0470 | 5/31/2023 |
| Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements | 0910–0606 | 5/31/2023 |
| Tracking Network for PETNet, LivestockNet, and SampleNet | 0910–0680 | 5/31/2023 |
| Center for Tobacco Products, Food and Drug Administration Funded Trainee/Scholar Survey | 0910–0887 | 5/31/2023 |
| Importer's Entry Notice | 0910–0046 | 6/30/2023 |
| Premarket Notification Submission 510(k), Subpart E | 0910–0120 | 6/30/2023 |
| Medical Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations | 0910–0748 | 6/30/2023 |
| Controlled Correspondence Related to Generic Drug Development | 0910–0797 | 6/30/2023 |
| Certification of Identity for Freedom of Information Act and Privacy Act Requests | 0910–0832 | 6/30/2023 |
| FDA Advisory Committee Membership Nominations | 0910–0833 | 6/30/2023 |

Dated: July 6, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020–14875 Filed 7–9–20; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2020–N–1391]**

### Office of Women's Health Strategic Priorities; Establishment of a Public Docket; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is opening a public docket to solicit input and comments from stakeholders interested in informing strategic priorities for the Office of Women's Health (OWH). This will help the Agency ensure that important health concerns are carefully considered in establishing OWH's scientific, educational, and outreach priorities.

**DATES:** Submit either electronic or written comments by September 8, 2020.

**ADDRESSES:** You may submit comments as follows. Please note that untimely comments will not be considered. Electronic comments must be submitted on or before September 8, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 8, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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,