

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

[Docket No. FDA-2011-N-0017]

### 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 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 (the 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 the information collection provisions of the Voluntary National Retail Food Regulatory Program Standards.

**DATES:** Submit either electronic or written comments on the collection of information by April 21, 2020.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 21, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 21, 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, 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-2011-N-0017 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.

- **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.

**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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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—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.

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 <sup>1</sup> .	16
No. 2: Trained Regulatory Staff .....	Self-Assessment: Completion of CFP Field Training Manual and Documentation of Successful Completion—Field Training Process; completion of summary worksheet of each employee training records <sup>1 2</sup> .	19.3
No. 3: HACCP Principles .....	Self-Assessment: Completion of worksheet documentation <sup>1</sup> .....	4
No. 4: Uniform Inspection Program .....	Self-Assessment: Completion of worksheet documentation of jurisdiction's quality assurance procedures <sup>1 2</sup> .	19
No. 5: Foodborne Illness Investigation .....	Self-Assessment: Completion of worksheet documentation <sup>1</sup> .....	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 <sup>1</sup> .	19
No. 7: Industry & Community Relations ...	Self-Assessment: Completion of worksheet <sup>1</sup> .....	2

TABLE 1—SELF ASSESSMENT—Continued

Standard	Recordkeeping activity	Hours per record
No. 8: Program Support and Resources ..	Self-Assessment: Selection and review of establishment files <sup>1</sup> .....	8
Total .....	.....	92.3

<sup>1</sup> Or comparable documentation.

<sup>2</sup> 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 <sup>1</sup> .....	333

<sup>1</sup> 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

Standard	Recordkeeping activity	Hours per record
Administrative Procedures .....	Verification Audit <sup>1</sup> .....	46.15

<sup>1</sup> 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 <sup>1</sup>

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping for FDA Worksheets <sup>2</sup> .....	500	1	500	94.29	47,145

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> 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 of this document) 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; 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; 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 <sup>1</sup>

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

<sup>1</sup> 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 in this document, 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: February 10, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020-03464 Filed 2-20-20; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-1066]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Annual Reporting for Custom Device Exemption

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) 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 the annual reporting for custom devices.

**DATES:** Submit either electronic or written comments on the collection of information by April 21, 2020.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 21, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 21, 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.

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- 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”).

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- 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-2017-N-1066 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Annual Reporting for Custom Device Exemption.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as