response are based on the average of these estimates.

Dated: January 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02190 Filed 1–31–14; 8:45 am]

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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) 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 4, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), 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)

The Voluntary National Retail Food Regulatory 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 those State, local, territorial, tribal and Federal regulatory programs that meet the Program Standards. The program elements addressed by the Program Standards are as follows: (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 to FDA on Form FDA 3519, ''FDA National Registry Report'' and Form FDA 3520, ''Permission to Publish in National Registry.'' These forms are provided in the Program Standards document, and are also provided on FDA's Web site at: *http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/default.htm.* 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 forms.

In April 2012, the Conference for Food Protection recommended that FDA make two changes to the Program Standards. The changes have been incorporated into the 2013 version, the draft of which is available on FDA's Web site. The first change was the addition of a new criterion in Standard 9. In order to show conformance with Standard 9, jurisdictions must implement an intervention strategy to address risk factors identified in the risk factor study, and then assess the effectiveness of the intervention strategy through subsequent risk factor studies or other similar tools. The second change was the creation of an Administrative Procedures document. The procedures for enrolling and participating in the Program Standards were previously included in Standard 9, along with other criteria specific to conducting a risk factor study. Stakeholders requested that information pertaining to enrollment and participation in the Program Standards be included in a separate, stand-alone document. Therefore, the information about the administration of the Program Standards, previously in Standard 9, is now provided in the Administrative Procedures document.

FDA analyzed whether incorporation of these two changes alters its estimate of the recordkeeping and reporting burdens. FDA concluded that there will be no change to the annual recordkeeping burden estimate. In the course of their normal activities, State, local, territorial, tribal, and Federal regulatory agencies already implement and document intervention strategies to address identified risk factors at regulated food establishments. The intention of the new criterion in Standard 9 is twofold: (1) To ensure that development and implementation of the intervention strategy is guided by data collected through the risk factor study, or other similar tools and (2) to ensure that the regulatory agency considers the effectiveness of the implemented intervention strategy in light of subsequent data. FDA notes that jurisdictions have the option to analyze their inspection data as indicated by the Standard 9 criteria, in lieu of conducting a risk factor study. This is a less resource-intensive method for tracking risk factor trends over time. However, the Agency has not changed its estimate of 333 hours for Standard 9 shown in Table 2 of this document. The Agency will reevaluate its estimate based on data it receives in the future from participating jurisdictions. As stated in the preceding paragraph, the second change resulted in the relocation of existing information from Standard 9 to the Administrative Procedures document in the 2013 version of the Program Standards. Because there were no changes to content, there will be no changes to the annual recordkeeping burden. The two noted changes had no effect on the reporting burden hour estimates shown in Table 2 of this document.

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 of this document), FDA considered responses from four State and three local jurisdictions that participated in an FDA Program Standards Pilot study. Table 2 of this document shows the estimated recordkeeping burden for the completion of the baseline data collection, and Table 3 of this document shows the estimated recordkeeping burden for the verification audit.

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 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—BASELINE 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% of time spent to complete self-assessment of all 9 Standards is spent completing verification audit worksheets. Time will be considerably less if less than 9 standards require verification audits.

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

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. As of September 30, 2013, 563 jurisdictions were enrolled in the Program Standards. However, 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 of this document.

Reporting

FDA requires regulatory jurisdictions that participate in the Program Standards to submit two forms annually: Form FDA 3519, ''FDA National Registry Report,'' and Form FDA 3520, ''Permission to Publish in National Registry.'' Form FDA 3519 requires the name and address of the jurisdiction; completion dates for the self-assessment, risk factor study (original and update), and verification audit; names of the person(s) who completed the self-assessment, verification audit, risk factor study (baseline report), risk factor study (update), and action plan; signature of the program manager; and date the form was completed. Form FDA 3520 requires the name and address of the jurisdiction, contact information for the enrollee's designated contact person, completion date of the self-assessment, date of the verification audit report, name of the auditor, signature of the official completing the form, and date the form was completed.

The reporting burden in Table 5 of this document includes only the time necessary to fill out and send the forms, as compiling the underlying information (including self-assessment reports, baseline surveys, outside audits, and supporting documentation) is accounted for under the recordkeeping estimates in Table 4 of this document.

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

TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of ''FDA National Registry Report''	3519	500	1	500	0.1	50
Submission of ''Permission to Publish in National Registry''	3520	500	1	500	0.1	50
Request for documentation of successful completion of staff training	Conference for Food Protection Training Plan and Log	500	3	1,500	0.1	150
Total						250

[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 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 12 minutes annually for each enrolled jurisdiction to complete both forms. FDA bases its estimate on the small number of data elements on the two forms and the ease of availability of the information. FDA estimates that, annually, 500 regulatory jurisdictions will submit one Form FDA 3519 for a total of 500 annual responses. Each submission is estimated to take 0.1 hour per response for a total of 50 hours. FDA estimates that, annually, 500 regulatory jurisdictions will submit one Form FDA 3520 for a total of 500 annual responses. Each of these submissions is estimated to take 0.1 hour per response for a total of 50 hours. 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 per response for a total of 150 hours. Thus, the total reporting burden for this information collection is 250 hours.

Dated: *January 29, 2014.*

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

American Glaucoma Society/Food and Drug Administration Workshop on Supporting Innovation for Safe and Effective Minimally Invasive Glaucoma Surgery; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''American Glaucoma Society (AGS)/FDA Workshop on Supporting Innovation for Safe and Effective Minimally Invasive Glaucoma Surgery.'' This workshop will address the current challenges in the assessment of implantable minimally invasive glaucoma surgical (MIGS) devices with a focus on clinical trial design and conduct. Glaucoma experts will present evidence to better define the appropriate patient population, as well as the appropriate evaluation of effectiveness and safety for MIGS devices. The primary goal of the workshop is to discuss the appropriate clinical trial design and conduct for MIGS devices in order to facilitate bringing these innovative technologies to the U.S. marketplace.

Date and Time: The public workshop will be held on February 26, 2014, from 1 p.m. to 6 p.m. Materials may be picked up starting at 12 noon.

Location: The public workshop will be held at the Washington Marriott at Metro Center, 775 12th St. NW., Washington, DC 20005.

Contact: Michelle Tarver, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2504, Silver Spring, MD 20993, 301–796–5620, FAX: 301–847–8126, email: *michelle.tarver@fda.hhs.gov.*

Registration: AGS will charge a registration fee to cover its share of the expenses associated with the workshop. The registration fee is $150 for AGS members and $300 for non-members in advance. Registration is available on a first-come, first-served basis. Persons interested in attending this public workshop may register online or by telephone. The deadline for online registration is February 10, 2014, at 5 p.m. EDT. There will be onsite registration on the day of the public workshop with the cost of onsite registration being $150 for AGS members and $500 for non-members. Early registration is recommended because facilities are limited.

If you need special accommodations due to a disability, please contact Ms. Susan Monahan at *susan.monahan@fda.hhs.gov* or 301–796–5661 no later than February 3, 2014.

To register for the public workshop, please visit the AGS Web site (*http://www.americanglaucomasociety.net/professionals/events/*). Those interested in attending but unable to access the electronic registration site should contact AGS Customer Service to register at 415–561–8587 or 866–561–8558 (toll free). Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. If there are any questions with registration, please contact the AGS administrative offices at 415–561–8587 or email to the attention of Amber Mendez at *ags@aao.org.* Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Food and beverages will be available for purchase by participants during the workshop breaks.

For more information on the workshop, please see the FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.)

Streaming Webcast of the Public Workshop: This public workshop will not be Webcast.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcript will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

SUPPLEMENTARY INFORMATION:

I. Background

Glaucoma is estimated to be the second leading cause of blindness worldwide. Management of this often chronic disease is a challenge for both patients and health care providers, requiring the use of multiple modalities including drops, lasers, and surgery. In recent years, innovative devices have been developed to decrease the risk of glaucoma surgery. These MIGS devices have moved the option for surgical intervention towards less severe forms of the disease. Hence, the appropriate clinical trial design and conduct for the evaluation of the safety and effectiveness of MIGS devices has become a topic of debate. At this workshop, we will discuss the important clinical trial components including subject enrollment criteria, safety parameters, and effectiveness endpoints. The workshop seeks to involve industry and academia in addressing the challenges in the development of appropriate clinical trials to adequately evaluate safety and