use a real TV show clip that is closer to 5 minutes long, which is the length of a typical news story segment. Third, we will include two additional, ''real'' advertisements, rather than just showing the experimental ad.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Eye tracking study of DTC prescription drug advertisement viewing	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pilot Study Screener	200	1	200	0.03 (2 minutes)	6
Main Study Screener	2,000	1	2,000	0.03 (2 minutes)	60
Pilot Study	30	1	30	1	30
Main Study	300	1	300	0.50 (30 minutes)	150
Total					246

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–12281 Filed 5–27–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1619]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On February 27, 2014, the Agency submitted a proposed collection of information entitled ''Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements'' to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0606. The approval expires on May 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: May 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–12293 Filed 5–27–14; 8:45 am]

BILLING CODE 4164–01–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: Fax written comments on the collection of information by June 27, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0621. Also include the FDA 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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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

The Voluntary National Retail Food Regulatory Program Standards (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, ''Release Record and Agreement—Permission to Publish in National Registry (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 (CFP) recommended that FDA make two changes to the Program Standards. The changes have been incorporated into the 2013 version, the draft of which will be 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 two-fold: (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

TABLE 1—SELF-ASSESSMENT—Continued

Standard	Recordkeeping activity	Hours per record
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 and 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 nine Standards is spent completing verification audit worksheets. Time will be considerably less if less than nine 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.

In the **Federal Register** of February 3, 2014 (79 FR 6200), FDA 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 5—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Form FDA	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 (6 minutes)	50
Submission of "Permission to Publish in National Registry".	3520	500	1	500	0.1 (6 minutes)	50
Request for Documentation of Successful Completion of Staff Training.	Conference for Food Protection Training Plan and Log.	500	3	1,500	0.1 (6 minutes)	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 over the past 14 years. 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 (6 minutes) 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 (6 minutes) per response for a total of 50 hours. FDA estimates that annually 500 regulatory jurisdictions will submit 3 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 (6 minutes) per response for a total of 150 hours. Thus, the total reporting burden for this information collection is 250 hours.

Dated: May 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–12289 Filed 5–27–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0639]

Agency Information Collection Activities; Proposed Collection; Comment Request; Notification of the Intent To Use an Accredited Person Under the Accredited Persons Inspection Program

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 eligibility criteria and the process to be followed by establishments when notifying FDA of a manufacturer's intent to have an accredited third party conduct a quality systems regulation inspection of their establishment instead of FDA, under the Accredited Persons (AP) Inspection Program.

DATES: Submit either electronic or written comments on the collection of information by July 28, 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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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