400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@FDA.HHS.GOV.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 18, 2010 (75 FR 63834), the Agency announced that the proposed information collection had been submitted 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 0910–0073. The approval expires on December 31, 2013. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: January 6, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–455 Filed 1–11–11; 8:45 am]

BILLING CODE 4160–01–P

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 March 14, 2011.

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: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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 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, and tribal 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 compliance with the standard (referred to in the Program Standards document as "quality records") and has one or more corresponding appendices that contain 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, and tribal government 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, and tribal 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 and 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, and tribal regulatory Agencies, and which can serve as quality records under the Program Standards.

State, local, and tribal 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 baseline survey 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 located in Appendix I of the Program Standards document. If a regulatory Agency follows all the recordkeeping recommendations in the individual standards and their appendices, it will have all the information needed to complete the forms.

In April 2010, the Conference for Food Protection approved changes to the Program Standards. The changes have been incorporated into a draft 2011 revision, which will be available at: *http://www.fda.gov/retailfoodprotection.* One change was to provide an extension of time for completion of the three management tasks. Another change was the inclusion of clarifying language in Standard 9 that a jurisdiction may use its inspection data to conduct its study of risk factor occurrence. Although this was always the intent in Standard 9, it was not clear to jurisdictions that this was a viable option.

FDA analyzed whether incorporation of these changes alters its estimate of the recordkeeping and reporting burdens. FDA concluded that the changes will lessen the annual recordkeeping burden estimate because the management tasks will be conducted on a less frequent basis annually. Thus, based on its experience with the Program Standards over the past 3 years, FDA has reduced its estimate of the hours per record to 94.29, from the previously estimated 157 hours per record in 2008. The reduced recordkeeping burden hour estimates are shown in table 4 of this document. FDA notes that jurisdictions that choose to analyze their inspection data per the Standard 9 criteria will enjoy a less resource intensive method for tracking risk factor trends over time. However, the Agency has not reduced its estimate of 333 hours for Standard 9 shown in table 2 of this document. The Agency will consider reducing this estimate in a future information collection request based on supporting data it expects to receive in the future from participating jurisdictions. 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, or tribal 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. Worksheets (Appendices) 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: (Appendix A) Completion of worksheet recording results of evaluations and comparison on worksheets[1].	16
No. 2—Trained Regulatory Staff	Self Assessment: (Appendix B–2 and B–4)[1] Completion of CFP Field Training Manual and Documentation of Successful Completion—Field Training Process; completion of summary worksheet of each employee training records[2].	19.3
No. 3—HACCP Principles	Self Assessment: (Appendix C[1]) Completion of worksheet documentation	4
No. 4—Uniform Inspection Program	Self Assessment: (Appendix D[1]) Completion of worksheet documentation of jurisdiction's quality assurance procedures[2].	19
No. 5—Foodborne Illness Investigation	Self Assessment: (Appendix E[1]) Completion of worksheet documentation	5
No. 6—Compliance Enforcement	Self Assessment: (Appendix F[1])	19
	Selection and review of 20 to 70 establishment files @ 25 minutes per file. Estimate is based on a mean number of 45. Completion of worksheet.	
No. 7—Industry & Community Relations	Self Assessment: (Appendix G[1]) Completion of worksheet	2
No. 8—Program Support and Resources	Self Assessment: (Appendix H[1]) Selection and review of establishment files	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	Baseline Data Collection (Appendices I & J) Selection and inspection of randomly selected statistical sample of 9 to 87 establishments from each of 9 facility types[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

Standard	Recordkeeping activity	Hours per record
No. 9	Verification Audit (Appendices I & J)[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]

FDA worksheets [2]	Number of recordkeepers	Annual frequency per record-keeping	Total annual records	Hours per record	Total hours
Appendices A through J	500	1	500	94.29	47,145
Total					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 3 years. FDA estimates that approximately 500 regulatory jurisdictions will participate in the Program Standards. 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, baseline data collection, 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). As noted, based on its experience with the Program Standards over the past 3 years, FDA has reduced its estimate of the number of recordkeeping hours that enrolled jurisdictions will perform annually to 94.29, from the previously estimated 157 hours per record in 2008. FDA estimates that, annually, 500 recordkeepers will spend 94.29 hours performing the required recordkeeping for a total of 47,145 hours.

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, baseline survey (original and update), and verification audit; names of the person(s) who completed the self-assessment, verification audit, baseline survey, baseline survey update, and action plan; signature of the program manager; and date the form was completed. Form FDA 3520 requires the name of the jurisdiction, completion date of the self assessment, date of the verification audit report, name of the auditor, signature and title 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]

Form FDA No.	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
3519	500	1	500	0.1	50
3520	500	1	500	0.1	50
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 over the past 3 years. As explained previously in this document, FDA estimates that 500 regulatory jurisdictions will enroll in the Program Standards. 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 5, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–458 Filed 1–11–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0468]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions

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 February 11, 2011.

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 e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0233. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@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. Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions—(OMB Control Number 0910–0233)—Extension

FDA's patent extension activities are conducted under the authority of the Drug Price Competition and Patent Term Restoration Act of 1984 (21 U.S.C. 355(j)) and the Animal Drug and Patent Term Restoration Act of 1988 (35 U.S.C. 156). New human drug, animal drug, human biological, medical device, food additive, or color additive products regulated by the FDA must undergo FDA safety, or safety and effectiveness, review before marketing is permitted. Where the product is covered by a patent, part of the patent's term may be consumed during this review, which diminishes the value of the patent. In enacting the Drug Price Competition and Patent Term Restoration Act of 1984 and the Animal Drug and Patent Term Restoration Act of 1988, Congress sought to encourage development of new, safer, and more effective medical and food additive products. It did so by authorizing the U.S. Patent and Trademark Office (PTO) to extend the patent term by a portion of the time during which FDA's safety and effectiveness review prevented marketing of the product. The length of the patent term extension is generally limited to a maximum of 5 years, and is calculated by PTO based on a statutory formula. When a patent holder submits an application for patent term extension to PTO, PTO requests information from FDA, including the length of the regulatory review period for the patented product. If PTO concludes that the product is eligible for patent term extension, FDA publishes a notice that describes the length of the regulatory review period and the dates used to calculate that period. Interested parties may request, under § 60.24 (21 CFR 60.24), revision of the length of the regulatory review period, or may petition under § 60.30 (21 CFR 60.30) to reduce the regulatory review period by any time where marketing approval was not pursued with "due diligence."

The statute defines due diligence as "that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period." As provided in § 60.30(c), a due diligence petition "shall set forth sufficient facts, including dates if possible, to merit an investigation by FDA of whether the applicant acted with due diligence." Upon receipt of a due diligence petition, FDA reviews the petition and evaluates whether any change in the regulatory review period is necessary. If so, the corrected regulatory review period is published in the **Federal Register**. A due diligence petitioner not satisfied with FDA's decision regarding the petition may, under § 60.40 (21 CFR 60.40), request an informal hearing for reconsideration of the due diligence determination. Petitioners are likely to include persons or organizations having knowledge that FDA's marketing permission for that product was not actively pursued throughout the regulatory review period. The information collection for which an extension of approval is being sought is the use of the statutorily created due diligence petition.

Since 1992, 12 requests for revision of the regulatory review period have been submitted under § 60.24. For 2007, 2008, and 2009, a total of three, or one per year, have been submitted under § 60.24. Two regulatory review periods have been altered. During that same time period, two due diligence petitions were submitted to FDA under § 60.30, for an average of fewer than one per year. There have been no requests for hearings under § 60.40 regarding the decisions on such petitions; however, for purposes of this information collection approval, we are estimating that we may receive one submission annually.

In the **Federal Register** of October 5, 2010 (75 FR 61493), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received on the information collection.

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