information as well as the adoption of electronic recordkeeping and electronic submission of data to the agency; and, review of product tracing procedures should be part of standard audits.

(Response) FDA agrees that recordkeeping is key to effective product tracing. However, to the extent that the comments suggest changes to the requirements of the recordkeeping regulations in sections 1.326 through 1.363, such requests are outside the scope of the four collection of information topics on which the notice solicits comments. Such changes to the current recordkeeping requirements can only be accomplished by notice and comment rulemaking.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
1.337, 1.345, and 1.352 (Records maintenance)	379,493	1	379,493	13.228	5,020,000
1.337, 1.345, and 1.352 (Learning for new firms)	18,975	1	18,975	4.790	90,890
Total					5,110,890

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

This estimate is based on FDA's estimate of the number of facilities affected by the final rule entitled "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," published in the **Federal Register** of December 9, 2004 (69 FR 71562 at 71630). With regard to records maintenance, FDA estimates that approximately 379,493 facilities will spend 13.228 hours collecting, recording, and checking for accuracy of the limited amount of additional information required by the regulations, for a total of 5,020,000 hours annually. In addition, FDA estimates that new firms entering the affected businesses will incur a burden from learning the regulatory requirements and understanding the records required for compliance. In this regard, the Agency estimates the number of new firms entering the affected businesses to be 5 percent of 379,493, or 18,975 firms. Thus, FDA estimates that approximately 18,975 facilities will spend 4.790 hours learning about the recordkeeping and records access requirements, for a total of 90,890 hours annually. Therefore, the total annual recordkeeping burden is estimated to be 5,110,890 hours.

Dated: March 23, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–7188 Filed 3–25–11; 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; 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 (the PRA).

DATES: Fax written comments on the collection of information by April 27, 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 0910–0621. Also include the FDA 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: 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 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 1 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 1–8, 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.

In the **Federal Register** of January 12, 2011 (76 FR 2124), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received six comment letters in response to the notice. One comment was generally supportive of the necessity of the information collection and its practical utility. Five letters contained comments outside the scope of the four collections of information topics on which the notice solicits comments and thus, will not be addressed here.

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

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 the Center for Food Protection 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. Hazard Analysis and Critical Control Point.	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]) 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.	19
No. 7. Industry & Community Relations.	Self Assessment: (Appendix G [1]) Completion of worksheet	2

TABLE 1—SELF ASSESSMENT—Continued

Standard	Recordkeeping activity	Hours per record
No. 8. Program Support and Resources.	Self Assessment: (Appendix H [1]) Selection and review of establishment files	8
Subtotal		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.

Thus, FDA estimates the recordkeeping burden for this collection of information as follows:

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

FDA Worksheets [2]	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
Appendices A–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 1 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	Number of responses per respondent	Total annual respondents	Average burden per response (in Hours) [2]	Total hours
3519	500	1	500	1/60	50
3520	500	1	500	1/60	50
CFP Training Plan and Log	500	3	1,500	1/60	150
Total					250

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

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: *March 23, 2011.*

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–7191 Filed 3–25–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0148]

Clarifying Edits to Existing Special Controls Guidance Documents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of updated special controls guidance documents for class II devices, which contain edits that reflect the Agency's effort to clarify questions and confusion regarding its position on the binding nature of special controls guidance documents. The revised language does not change the Agency's position or view, but rather is intended to clarify its position and remedy any possible confusion or misunderstanding.

DATES: Submit either electronic or written comments on this document at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for electronic access to affected documents.

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

FOR FURTHER INFORMATION CONTACT: Philip Desjardins, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5452, Silver Spring, MD 20993–0002, 301–796–5678; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In December 2008, FDA revised the cover sheet and standard language in newly issued special controls guidance documents to clarify the effect of a guidance that has been established as a special control ("special controls guidance"). In order to comply with the special controls guidance, manufacturers must address each identified risk to health presented in the guidance for the class II device by either meeting the recommendations of the guidance or by some other means that provides equivalent assurances of safety and effectiveness.

FDA is now updating all pre-December 2008 special controls guidance documents with the revised standard language. Revisions to the special controls guidance documents include clarifying the statement of the special controls guidance document's effect by replacing the standard language with the following statement: "The firm must show that its device addresses the issues of safety and effectiveness identified in this guidance, either by meeting the recommendations of this guidance or by some other means that provides equivalent assurances of safety and effectiveness."

Special controls guidance documents on the following topics have been affected: [1]

1. Acute Upper Airway Obstruction Devices,
2. Clitoral Engorgement Devices,
3. Anti-*Saccharomyces cerevisiae* (*S. cerevisiae*) Antibody (ASCA) Premarket Notifications,
4. Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis,
5. B-Type Natriuretic Peptide Premarket Notifications,
6. Home Uterine Activity Monitors,
7. Pharmacy Compounding Systems,
8. Tissue Culture Media for Human ex vivo Tissue and Cell Culture Processing Applications,
9. Indwelling Blood Gas Analyzers,
10. Ingestible Telemetric Gastrointestinal Capsule Imaging System,
11. Premarket Notifications for Automated Differential Cell Counter for Immature or Abnormal Blood Cells,
12. Medical Washers and Medical Washer-Disinfectors,

[1] All guidance titles throughout this document reflect the style of the published versions.