information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: January 8, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. 08–96 Filed 1–14–08: 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0419]

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 February 14, 2008.

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: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title, Voluntary National Retail Food Regulatory Program Standards. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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

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). All three tasks must initially be completed within a 3-year time span. 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. The time required to complete the forms is minimal.

In the **Federal Register** of November 14, 2006 (71 FR 66337), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received two letters in response to the notice, but the letters contained comments that were not responsive to the four PRA comment requests. These comments will not be addressed in this document.

In April 2006, the Conference for Food Protection approved changes to the Program Standards that have been incorporated into a draft 2007 revision, which is available at *http://www.cfsan.fda.gov/~dms/ret4toc.html*. FDA analyzed whether incorporation of the changes alters its estimate of the recordkeeping and reporting burdens as set forth in the 60-day notice. FDA concluded that the changes cause a minor increase and decrease in the recordkeeping burden, resulting in no net change in the recordkeeping burden estimate. FDA further concluded that the reporting burden estimate should be increased by adding a line to table 2 to reflect the addition of 150 hours. This is because the revision to Standard 2 establishes an Assessment of Training Needs (ATN) process and forms that can be used by regulatory retail food program managers/training officers to prepare Food Safety Inspection officers (FSIOs) to conduct retail food and foodservice inspections (new Appendix B–2 and its accompanying Attachments

A and B). As part of the jurisdiction's usual and customary 25 joint field inspections, the jurisdiction's trainer will conduct at least 1 Assessment of Training Needs (ATN) per new hire. The ATN is a systematic evaluation of the new hire's knowledge, skills, and abilities that are needed before being able to conduct independent inspections. Following the ATN, the jurisdiction's trainer is made aware of any training deficiencies that need to be corrected prior to allowing the new hire to conduct independent work. Regulatory jurisdictions have the flexibility in the ATN to customize training so that it reflects a jurisdiction's administrative policies, sampling procedures, and inspection protocol. The ATN provides two forms to assist food program managers/trainers e forms provide both the candidate and the trainer feedback on specific elements of effective institutional foodservice, restaurant, and retail food store inspections. The forms are (1) Retail Food, Restaurant, and Institutional Foodservice — Food Safety Inspection Officer, Field Training Worksheet [this form provides a representative baseline of competencies (criteria) expected to be performed by regulatory retail food program FSIOs]. It is to be used during joint field training inspections and is completed as a part of the usual duties of the jurisdiction]; and (2) Retail Food, Restaurant, and Institutional Foodservice — Food Safety Inspection Officer, Documentation of Successful Completion [this form provides verification that the FSIO has successfully demonstrated the ability to perform all the required competencies (criteria) needed to conduct independent retail food and foodservice inspections. It is completed once at the end of the joint field training process.] FDA estimates that an additional 150 reporting burden hours will result from this change, as discussed later this document. In addition, FDA has increased the recordkeeping burden hour estimate from 157 to 157.1 based on the changes to the 2007 document in the areas of Self Assessment and Verification Audit.

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 chart 1 of this document), FDA considered responses from four state and three local jurisdictions that participated in an FDA Program Standards Pilot study. Chart 2 of this document shows the estimated recordkeeping burden for the completion of the baseline data collection and chart 3 of this document shows the estimated recordkeeping burden for the verification audit.

The overall program improvement cycle is a 3-year period for completion of all three management tasks.

CHART 1. YEAR ONE — SELF ASSESSMENT

Standard	Recordkeeping Activity	Hours per Recordkeeper (Year One)
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 ATN Field Training Worksheet 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]) 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
No. 8 Program Support and Resources	Self Assessment: (Appendix H[1]) Selection and review of establishment files	8
SUBTOTAL		92.3 Hours

[1] Or comparable documentation

[2] Estimates will vary depending on number of regulated food establishments and the number of inspectors employed by the jurisdiction.

CHART 2. YEAR TWO — BASELINE DATA COLLECTION

Standard	Recordkeeping Activity	Hours per Recordkeeper (Year Two)
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.

CHART 3. YEAR THREE — VERIFICATION AUDIT

Standard	Recordkeeping Activity	Hours per Recordkeeper (Year Three)
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 estimated the annual hours per recordkeeper (i.e., per enrolled jurisdiction) in table 1 of this document by adding the recordkeeping estimates for the management tasks of self assessment, baseline data collection, and verification audit (charts 1, 2, and 3 of this document) that enrolled jurisdictions must perform during a 3–year cycle (92.3 + 333 + 46.15 = 471.45, then dividing the total by three to obtain an annual average (471.45 / 3 = 157.1). The estimates in tables 1 and 2 of this document are based on the estimated participation of 500 regulatory jurisdictions in the Program Standards. Table 1 shows an increase of 50 hours in the overall recordkeeping burden estimate based on a 0.1 increase in the estimate of annual hours per recordkeeper in the 2007 document. 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 in the near future. In its 2002 operational plan, the FDA National Retail Food Team established a goal of enrolling 15 percent of eligible agencies, or 450 programs, in the Program Standards by the year 2010. For purposes of this burden estimate, it is reasonable to take into account the possibility that this goal could be exceeded by approximately 10 percent, for a total of approximately 500 participating agencies.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

FDA Worksheets[2]	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Appendices A-J	500	1	500	157	78,550
Total Burden Hours					78,550

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

Reporting

Based on the number and nature of the items that need to be completed, FDA estimates a total of 12 minutes annually for each enrolled jurisdiction to complete both FDA Form 3519, ''FDA National Registry Report,'' and Form 3520, ''Permission to Publish in National Registry.'' Form 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 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.

FDA has added a line and 150 hours to table 2, due to the changes to the Program Standards approved by the 2006 Conference for Food Protection. Based on the two forms required for the ATN, the nature of the items that need to be completed, and the number of new hires, FDA estimates a total of 150 hours annually for completion of the completion ATN Field Training Worksheet and Documentation of Successful Completion — Field Training Process; (500 jurisdictions with 3 new hires per year at 6 minutes for completion of all forms equals 150 hours per year for completion of both Summary forms). As explained previously in this document, FDA estimates that 500 regulatory jurisdictions will enroll in the Program Standards. The reporting burden in table 2 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.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Forms	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3519	500	1	500	6 min	50 hours
3520	500	1	500	6min	50 hours
Retail Food, Restaurant, and Institutional Foodservice — FSIO, Documentation of Successful Completion	500	3	1,500	6 min	150 hours
Total Burden Hours					78,550

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

Dated: December 27, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–542 Filed 1–14–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0495]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device User Fee Amendments of 2007; Foreign Small Business Qualification Certification, FDA Form 3602A

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 FDA Form 3602A, which will allow a foreign business to qualify as a ''small business'' and pay certain medical device user fees at reduced rates.

DATES: Submit written or electronic comments on the collection of information by March 17, 2008.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments* or *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 the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472

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.

Medical Device User Fee Amendments of 2007; Foreign Small Business Qualification Certification, Form FDA 3602A—(21 U.S.C.379j) (OMB Control Number 0910–0613—Extension)

The FDA Amendments Act of 2007 includes the ''Medical Device User Fee Amendments of 2007'' (the 2007 Amendments), which reauthorizes medical device user fees for fiscal years (FY) 2008 through 2012 and which makes significant changes to the medical device user fee provisions of the act. The 2007 Amendments provide a new way for a foreign business to qualify as a small business eligible to pay a significantly-lower fee when a medical device user fee must be paid.

Before passage of the 2007 Amendments, the only way a business could qualify as a small business was to submit a Federal (U.S.) income tax return showing its gross receipts or sales that did not exceed a statutory threshold, currently, $100 million. If a business could not provide a Federal income tax return, it did not qualify as a small business and had to pay the standard (full) fee. Because many foreign businesses have not, and cannot, file a Federal (U.S.) income tax return, this requirement has effectively prevented those businesses from qualifying for the small business fee rates. Thus, foreign governments, including the European Union, have objected.

In lieu of a Federal income tax return, the 2007 Amendments will allow a foreign business to qualify as a small