sets and codes for establishment registration and drug listing information, including labeling. The information collection resulting from this guidance, discussed in the **Federal Register** of January 8, 2009 (74 FR 816), has been approved by OMB under Control Number 0910–0045. As discussed in the January 8, 2009, **Federal Register** notice, to create an SPL file and submit it to FDA, a registrant would need the following tools: A computer, appropriate software, access to the Internet, knowledge of terminology and standards, and access to FDA's electronic submission gateway (ESG). Registrants (and most individuals) have computers and Internet access available for their use. If a business does not have an available computer or access to the Internet, free use of computers and the Internet are usually available at public facilities, e.g., a community library. In addition, there should be no additional costs associated with obtaining the appropriate software. In 2008, FDA collaborated with GlobalSubmit to make available free SPL authoring software that SPL authors may utilize to create new SPL documents or edit previous versions. (Information on obtaining this software is explained in section IV.A of the guidance ''Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Listing.'') In addition to the software, FDA also provides technical assistance and other resources, code sets and codes, and data standards regarding SPL files.

After the SPL file is created, the registrant would upload the file through the ESG, as explained in the January 8, 2009, **Federal Register** notice. A digital certificate is needed to use the ESG. The digital certificate binds together the owner's name and a pair of electronic keys (a public key and a private key) that can be used to encrypt and sign documents. A fee of up to $20.00 is charged for the digital certificate and the registrant may need to renew the certificate not less than annually. We are not calculating this fee as a cost for this extension because all applicants who submit content of labeling are also subject to the drug establishment registration and listing requirements and would have already acquired the digital certificate as a result of the May 2009 guidance on drug establishment registration and listing.

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

TABLE 1.

	Number of respondents	Annual frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Content of labeling submissions in NDAs, ANDAs, supplemental NDAs and ANDAs, and annual reports	450	11.11	5,000	1.25	6,250

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

Dated: October 29, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–26760 Filed 11–5–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''Collection of Information for Agency for Healthcare Research and Quality's (AHRQ) Hospital Survey on Patient Safety Culture Comparative Database.'' In accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on September 2nd, 2009 and allowed 60 days for public comment. One comment was received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by December 7, 2009.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by e-mail at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by e-mail at *doris.lefkowitz@ahrg.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Collection of Information for Agency for Healthcare Research and Quality's (AHRQ) Hospital Survey on Patient Safety Culture Comparative Database

The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) approve, under the Paperwork Reduction Act of 1995, AHRQ's collection of information for the AHRQ Hospital Survey on Patient Safety Culture (Hospital SOPS) Comparative Database. The Hospital SOPS Comparative Database consists of data from the AHRQ Hospital Survey on Patient Safety Culture. Hospitals in the U.S. are asked to voluntarily submit data from the survey to AHRQ, through its contractor, Westat. The database was developed by AHRQ in 2006 in response to requests from hospitals interested in knowing how their patient safety culture survey results compare to those of other hospitals in their efforts to improve patient safety.

In 1999, the Institute of Medicine called for health care organizations to develop a ''culture of safety'' in which their workforces and processes focus on improving the reliability and safety of care for patients (IOM, 1999; To Err is Human: Building a Safer Health

System). To respond to the need for tools to assess patient safety culture in health care, AHRQ developed and pilot tested the Hospital Survey on Patient Safety Culture with OMB approval (OMB No. 0935–0115; Approved 2/4/2003). The survey was designed to enable hospitals to assess staff opinions about patient safety issues, medical error, and error reporting and includes 42 items that measure 12 dimensions of patient safety culture. AHRQ released the survey in the public domain along with a Survey User's Guide and other toolkit materials in November 2004 on the AHRQ Web site. Since its release, the survey has been voluntarily used by hundreds of hospitals in the U.S.

The Hospital SOPS survey and the Hospital SOPS Comparative Database are supported by AHRQ to meet its goals of promoting improvements in the quality and safety of health care in hospital settings. This project is conducted pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to health statistics, surveys, and database development. See 42 U.S.C. 299a(a)(1) and (8). The surveys, toolkit materials, and comparative database results are all made available in the public domain along with technical assistance, provided by AHRQ through its contractor at no charge to hospitals, to facilitate the use of these materials for hospital patient safety and quality improvement.

Method of Collection

Information for the Hospital SOPS database has been collected by AHRQ on an annual basis since 2006. Hospitals are asked to voluntarily submit their Hospital SOPS survey data to the comparative database between May 1 and June 30. The data are then cleaned and aggregated and used to produce a Comparative Database Report that displays averages, standard deviations, and percentile scores on the survey's 42 items and 12 patient safety culture dimensions, as well as displaying these results by hospital characteristics (bed size, teaching status, ownership) and respondent characteristics (hospital work area, staff position, and those with direct interaction with patients). In addition, trend data, showing changes in scores over time, are presented from hospitals that have submitted to the database more than once.

Estimated Annual Respondent Burden

Hospitals administer the AHRQ Hospital Survey on Patient Safety Culture every 16 months on average. Therefore, the number of hospital submissions to the database varies each year because hospitals do not submit data every year. The 250 respondents/point-of-contacts (POCs) shown in Exhibit I are based on an estimated increase in the number of submissions in 2010 and 2011 (above the 180 respondents from 2009). Data submission is typically handled by one POC who is either a hospital patient safety manager or a survey vendor. The POC completes a number of data submission steps and forms, beginning with completion of an online Eligibility and Registration Form. The POCs typically submit data on behalf of 3 hospitals, on average, because many hospitals are part of a multi-hospital system that is submitting data, or the POC is a vendor that is submitting data for multiple hospitals. In 2009, 180 POCs submitted data on behalf of a total of 535 hospitals (an average of 3 hospital submissions per POC). Exhibits 1 and 2 are based on the estimated number of individual POCs who will complete the database submission steps and forms in the coming years, not based on the number of hospitals. The Patient Safety Improvement Initiatives Form is completed only by POCs from trending hospitals that have submitted data more than once, so only about half of the POCs each year will be asked to complete the form for each of the 3 hospitals (on average) they are submitting data for. The Hospital Information Form is completed by all POCs for each of their hospitals. The total annual burden hours are estimated to be 1,508.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data. The cost burden is estimated to be $69,438 annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

[Hours total]

Form name	Number of respondents/ POCs	Number of response per POCs	Response per response	Total burden hours
Eligibility/Registration Form and Data Submission*	250	1	5.6	1,400
Data Use Agreement	250	1	3/60	13
Patient Safety Improvement Initiatives Form (for trending hospitals only)	125	3	5/60	32
Hospital Information Form	250	3	5/60	63
Total	875	NA	NA	1,508

*The Eligibility and Registration Form requires 3 minutes to complete; however about 5.5 hours is required to prepare/plan for the data submission. This includes the amount of time POCs and other hospital staff (CEO, lawyer, database administrator) typically spend deciding whether to participate in the database and preparing their materials and data set for submission to the database, and performing the submission.

EXHIBIT 2—ESTIMATED ANNUALIZED COST HOURS

[Hours total]

Form name	Number of responses per POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Eligibility/Registration Form and Data Submission	250	1,400	$46.11	$64,554
Data Use Agreement	250	13	45.22	588
Patient Safety Improvement Initiatives Form (for trending hospitals only)	125	32	45.22	1,447
Hospital Information Form	250	63	45.22	2,849

EXHIBIT 2—ESTIMATED ANNUALIZED COST HOURS—Continued

[Hours total]

Form name	Number of responses per POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Total	875	1,508	NA	$69,438

*Wage rates were calculated using the mean hourly wage based on occupational employment and wage estimates from the Dept of Labor, Bureau of Labor Statistics' May 2008 National Industry-Specific Occupational Employment and Wage Estimates NAICS 622000—Hospitals, located at *http://www.bls.gov/oes/2008/may/naics3_22000.htm.* Wage rate of $46.22 is based on the mean hourly wages for Medical and Health Services Managers. Wage rate of $46.11 is the weighted mean hourly wage for: Medical and Health Services Managers ($45.22 x 2.6 hours = $117.57), Lawyers ($62.95 x .5 hours =$31 .48), Chief Executives ($89.16 x .5 hours = $44.58), and Database Administrators ($32.30 x 2 hours = $64.60) [Weighted mean = ($117.57 + 31.48 + 44.58 + 64.60)/5.6 hours = $258.2315.6 hours = $46.1 1/hour].

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated annualized cost to the government for developing, maintaining, and managing the database and analyzing the data and producing reports. The cost is estimated to be $250,000 annually.

EXHIBIT 3—ESTIMATED ANNUALIZED COST

Cost component	Annualized cost
Database Development and Maintenance	$50 000
Data Submission	75,000
Data Analysis & Reports	125,000
Total	250,000

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research, quality improvement and information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: October 21, 2009.

Carolyn M. Clancy,

Director.

[FR Doc. E9–26673 Filed 11–5–09; 8:45 am]

BILLING CODE M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0506]

Agency Information Collection Activities; Proposed Collection; Comment Request; Bar Code Label Requirement for Human Drug and Biological Products

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 bar code label requirements for human drug and biological products.

DATES: Submit written or electronic comments on the collection of information by January 5, 2010.

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: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, *Elizabeth.Berbakos@fda.hhs.gov*, 301–796–3792.

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.