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.

Bar Code Label Requirement for Human Drug and Biological Products (21 CFR Part 314) (OMB Control Number 0910–0537) Extension

In the **Federal Register** of February 26, 2004 (69 FR 9120), we issued new regulations that required human drug product and biological product labels to have bar codes. The rule required bar codes on most human prescription drug products and on over-the-counter (OTC) drug products that are dispensed pursuant to an order and commonly used in health care facilities. The rule also required machine-readable information on blood and blood components. For human prescription drug products and OTC drug products that are dispensed pursuant to an order and commonly used in health care facilities, the bar code must contain the National Drug Code number for the product. For blood and blood components, the rule specifies the minimum contents of the machine-readable information in a format approved by the Director, Center for Biologics Evaluation and Research as blood centers have generally agreed upon the information to be encoded on the label. The rule is intended to help reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time.

Most of the information collection burden resulting from the final rule, as calculated in table 1 of the final rule (69 FR 9120 at 9149), was a one-time burden that does not occur after the rule's compliance date of April 26, 2006. In addition, some of the information collection burden estimated in the final rule is now covered in other OMB-approved information collection packages for FDA. However, parties may continue to seek an exemption from the bar code requirement under certain, limited circumstances. Section 201.25(d) (21 CFR 201.25(d)) requires submission of a written request for an exemption and describes the contents of such requests. Based on the number of exemption requests we have received, we estimate that approximately two exemption requests may be submitted annually, and that each exemption request will require 24 hours to complete. This would result in an annual reporting burden of 48 hours.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	No. of Responses per Respodent	Total Annual Responses	Hours per Response	Total Hours
201.25(d)	2	1	2	24	48

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

Dated: November 2, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–26850 Filed 11–5–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Next Series of Tobacco Use Supplements to the Current Population Survey (TUS–CPS) (NCI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Next Series of Tobacco Use Supplements to the Current Population Survey (TUS–CPS). *Type of information request:* REINSTATEMENT WITH CHANGE of OMB #0925–0368, Expiration 4/30/2009. *Need and Use of Information Collection:* The 2010–2011 Tobacco Use Supplement to the Current Population Survey conducted by the Census Bureau will collect data from the U.S. civilian non-institutionalized population on smoking, other tobacco use, and attempts at cessation; policy information such as home and workplace smoking policies; health professional advice to stop smoking; and changes in smoking norms and attitudes. The TUS–CPS will be and has been in the past a key source of national, State, and some local-level data on these topics in U.S. households because it uses a large, nationally representative sample. This survey is part of a continuing series of surveys (OMB# 0925–0368) that were sponsored by National Cancer Institute (NCI) and has been administered triennially as part of the U.S. Census Bureau's and the Bureau of Labor Statistics CPS. The TUS–CPS has been fielded since 1992, most recently in 2006–07, and its data are available for public use. Government agencies, other researchers and the public can use the data to monitor progress in the control of tobacco use, conduct tobacco-related research, evaluate tobacco control programs, examine tobacco-use-related health disparities, and use this data to help determine policies and services that need to be provided. A unique feature is the ability to link other social and economic Census Bureau and Bureau of Labor Statistics data and other sponsor-supported supplement data to the TUS–CPS data. Much of this data can also be linked to cancer and other cause-specific mortality data through the National Longitudinal Mortality Study (co-sponsored by three NIH agencies, the National Center for Health Statistics/Centers for Disease Control and Prevention (CDC), and the Census Bureau). This survey has in the past, and the 2010–2011 survey, will provide in the future invaluable information to measure progress toward tobacco control as part of the (NCI's) Cancer Progress Report, and the Department of Health and Human Services' Healthy People 2010 and 2020 Goals. This data will also provide a basis for the National Human Genome Research Institute's PhenX Alcohol, Tobacco, and Other Substances Toolkit, provide long-term trend data for CDC and other State and local public health staff, and support the research of extramural scientists. The 2010–2011 TUS–CPS is also relevant to several NCI tobacco control initiatives. The main 2010–2011 survey will allow State and sub-State-specific estimates to be made as do all the previous surveys. The May 2011 Follow-Up questionnaire will consist of an abbreviated version of the main 2010–2011 questionnaire. Data will be collected in May 2010, August 2010, January 2011, and May 2011 from approximately 315,000 respondents (270,000 unique respondents, 45,000 of