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.

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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

these in the May 2011 Follow-Up). The 2010–2011 TUS–CPS, complemented by the Follow-Up questionnaire, will be useful for researchers interested in measuring the impact on tobacco cessation of new FDA regulation (the Family Smoking Prevention and Tobacco Control Act) as it is implemented, and will complement Federal tobacco research and policy efforts. *Frequency of Response:* One-time study for the main 2010–2011 survey; One-time study for the May 2011 Follow-Up. *Affected Public:* Individuals or households. *Type of Respondents:* Persons 18 years of age or older. The annualized cost to respondents is estimated at $285,000. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report. The annual reporting burden is presented in the table below.

TABLE—ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondent per survey period	Number of respondents (annualized)	Responses per respondent	Average time per response (minutes/hour)	Annual burden hours
May 2010: Individuals	30,000	1	9/60 (0.15)	4,500
August 2010: Individuals	30,000	1	9/60 (0.15)	4,500
January 2011: Individuals	30,000	1	9/60 (0.15)	4,500
May 2011 Follow-Up: Individuals	15,000	1	6/60 (0.10)	1,500
Totals	105,000			15,000

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Anne Hartman, M.S., M.A., Health Statistician, National Cancer Institute, 6130 Executive Blvd—MSC 7344, Executive Plaza North, Suite 4005, Bethesda, Maryland 20892–7344, or call non-toll free 301–496–4970, or FAX your request, to 301–435–3710, or e-mail your request, including your address, to *ah42t@nih.gov* or *hartmana@mail.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: November 2, 2009.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS 10198 and CMS–10296]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Creditable Coverage Disclosure to CMS On-Line Form and Instructions; *Use:* Most entities that currently provide prescription drug benefits to any Medicare Part D eligible individual must disclose to the CMS whether the prescription drug benefit that they offer is creditable. The disclosure is required to be provided annually and upon any change that affects whether the coverage is creditable prescription drug coverage. CMS released a Disclosure to CMS Guidance Paper and a disclosure to CMS notification on-line form in January 2006.

Section 1860D–1 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and implementing regulations at 42 CFR 423.56 require that entities that offer prescription drug benefits under any of the types of coverage described in 42 CFR 423.56 (b) provide a disclosure of creditable coverage to CMS informing us whether such coverage meets the actuarial requirements specified in guidelines provided by CMS. *Form Number:* CMS–10198 (OMB#: 0938–1013); *Frequency:* Reporting—Yearly and Semi-annually; *Affected Public:* Federal Government, Business or other for-profits and not-for-profit institutions, and State, Local, or Tribal Governments; *Number of Respondents:* 87,500; *Total Annual Responses:* 87,500; *Total Annual Hours:* 7,291.7. (For policy questions regarding this collection contact Louis Blank at 410–786–5511. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Electronic