section 403(r)(6) of the act. Section 403(r)(6) of the act requires that the agency be notified, with a submission about such statements, no later than 30 days after the first marketing of the dietary supplement. Information that is required in the submission includes the following items: (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) a signature of a responsible individual who can certify the accuracy of the information presented, and who must certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

The agency established § 101.93 (21 CFR 101.93) as the procedural regulation for this program. Section 101.93 provides details of the procedures associated with the submission and identifies the information that must be included in order to meet the requirements of section 403 of the act.

In the **Federal Register** of June 2, 2009 (74 FR 26406), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two letters in response, each containing one or more comments. One of these letters was received several months after the close of the comment period. The comments that were timely filed were outside the scope of the comment request.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
101.93	2,200	1	2,200	0.75	1,650

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

The agency believes that there will be minimal burden on the industry to generate information to meet the requirements of section 403 of the act in submitting information regarding section 403(r)(6) statements on labels or in labeling of dietary supplements. The agency is requesting only information that is immediately available to the manufacturer, packer, or distributor of the dietary supplement that bears such a statement on its label or in its labeling. FDA estimates that, each year, approximately 2,200 firms will submit the information required by section 403 of the act. We estimate that a firm will require 0.75 hours to gather the information needed and prepare a communication to FDA, for a total of 1,650 hours (2,200 x 0.75). This estimate is based on the average number of notification submissions received by the agency in the preceding 2 years.

Dated: January 20, 2010.

David Dorsey

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–1435 Filed 1–25–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Next Series of Tobacco Use Supplements to the Current Population Survey (TUS–CPS) (NCI)

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on November 6, 2009, (Vol. 74, No. 214, pp. 57496–97) and allowed 60 days for public comment. One request for information was received on November 6, 2009. A copy of the 2010–2011 TUS–CPS was e-mailed to the requestor reiterating our data collection plans as stated in the 60-day **Federal Register** Notice. Another comment was received on December 16, 2009 complimenting our inclusion in the 2010–2011 TUS–CPS of critically needed information on details about the types of cigars (especially small cigars) used by smokers and new and valuable information on menthol cigarette smoking. We thanked the requestor for the endorsement and agreed that we thought that was valuable and timely as well and that is why we have included the information in the proposed data collection. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Next Series of Tobacco Use Supplements to the Current Population Survey (TUS–CPS) (NCI). *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 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 Trend 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.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Attention: NIH Desk Officer, Office of Management and Budget, at *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. 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 30 days of the date of this publication.

Dated: January 15, 2010.

Kristine Miller,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2010–1425 Filed 1–25–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0019]

Agency Information Collection Activities; Proposed Collection; Comment Request; General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Forms FDA 356h and 2567

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