This document is scheduled to be published in the
Federal Register on 08/15/2012 and available online at
http://federalregister.gov/a/2012-20068, and on **FDsys.gov**

[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request

Population Assessment of Tobacco and Health (PATH) Study

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute on Drug Abuse (NIDA), 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 May 18, 2012, pages 29667-29668 and allowed 60-days for public comment. Two public comments were received. 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*:* Population Assessment of Tobacco and Health (PATH) Study. Type of Information Collection Request*:* NEW. Need and Use of Information Collection:

This is a large national longitudinal cohort study on tobacco use behavior and health in the United States conducted under the direction of the National Institutes of Health (NIH) National Institute on Drug Abuse (NIDA) and in partnership with the Food and Drug Administration (FDA). The field test is scheduled to begin in the fall of 2012 and the baseline collection is scheduled to begin in the fall of 2013. Using annual interviews and the collection of biospecimens from adults, the PATH study is designed to establish a population-based framework for monitoring and evaluating the behavioral and health impacts of regulatory provisions by FDA as it meets its mandate under the Family Smoking Prevention and Tobacco Control Act (FSPTCA) to regulate tobacco-product advertising, labeling, marketing, constituents, ingredients, and additives. These regulatory changes are expected to influence tobacco-product risk perceptions, exposures, and use patterns in the short term, and to reduce tobacco-related morbidity and mortality in the long term. By measuring and accurately reporting tobacco product use behaviors and health effects associated with these regulatory changes, this study will provide an empirical evidence base to inform the development, implementation, and evaluation of tobacco-product regulations in the U.S.

Frequency of Response: Annually. Affected Public: Individuals or households. Type of Respondents: Youth (ages 12-17) and Adults (ages 18+). The annual reporting burden for the field test is presented in Table 1, and the annual reporting burden for the baseline data collection is presented in Table 2. The annualized cost to respondents for the field test is estimated at: $22,993; and the annualized cost to respondents for the baseline data collection is: $1,792,156. There are no capital, operating, or maintenance costs.

Table 1 PATH Study Field Test Hour Burden Estimates

Type of Respondents	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours per Response	Estimated Total Annual Burden Hours Requested
Adults – Household Screener	1,295	1	17/60	367
Adults – Individual Screener	840	1	6/60	84
Adults – Extended Interview	590	1	1 9/60	679
Adults – Biospecimen Collection Forms	590	1	9/60	89
Adults – Tobacco Use Form	590	1	2/60	20
Adults – Followup/Tracking Participant Information Form	590	2	6/60	118
Youth – Extended Interview	100	1	35/60	58
Adult – Parent Interview	100	1	19/60	32
Adults – Followup/Tracking Participant Information Form for Youth (completed by parents)	100	2	8/60	27
Total				1,446

Table 2 PATH Study Baseline Hour Burden Estimates

Type of Respondents	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours per Response	Estimated Total Annual Burden Hours Requested
Adults – Household Screener	100,983	1	17/60	28,612
Adults – Individual Screener	63,000	1	6/60	6,300
Adults – Extended Interview	42,730	1	1 9/60	49,140
Adults – Biospecimen Collection Forms	42,730	1	9/60	6,410
Adults – Tobacco Use Form	42,730	1	2/60	1,424
Adults – Followup/Tracking Participant Information Form	42,730	2	6/60	8,546
Youth – Extended Interview	16,857	1	35/60	9,833
Adult – Parent Interview	16,857	1	19/60	5,338
Adults – Followup/Tracking Participant Information Form for Youth (completed by parents)	16,857	2	8/60	4,495
Total				115,602

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) 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) 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) 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 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: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Kevin P. Conway, Ph.D., Deputy Director, Division of Epidemiology, Services, and Prevention Research, National Institute on Drug Abuse, 6001 Executive Blvd., Room 5185; 301-443-8755; email PATHprojectofficer@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.

Signed_____ Dated: August 7, 2012

Glenda J. Conroy

Executive Officer (OM Director) NIDA

[FR Doc. 2012-20068 Filed 08/14/2012 at 8:45 am; Publication Date: 08/15/2012]