[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 60-day Comment Request; Population Assessment of Tobacco and Health Study

AGENCY: National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH), Department of Health and Human Services.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute on Drug Abuse (NIDA), 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.

DATES: *Comment 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.

FOR FURTHER INFORMATION CONTACT: *To Submit Comments and for Further Information:* To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project,

contact: Dr. Kevin P. Conway, Deputy Director, Division of Epidemiology, Services, and Prevention Research, NIDA, NIH, 6001 Executive Boulevard, Room 5185, Rockville, MD 20852; or call non-toll-free number (301) 443-8755 or E-mail your request, including your address to: PATHprojectofficer@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION:

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.

Proposed Collection: Cognitive Interviews and Focus Groups for the Population Assessment of Tobacco and Health (PATH) Study (NIDA), 0925-0663-Revision, National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA).

Need and Use of Information Collection: This is a revision request (OMB 0925-0663, expires 11/30/2015) for the Population Assessment of Tobacco and Health (PATH)

Study to conduct cognitive interviews and focus groups, to support the development of the Study's questionnaires and other materials. The PATH Study is a national longitudinal cohort study of tobacco use behavior and health among the U.S. household population of adults age 18 and older and youth ages 12 to 17; the Study conducts annual interviews and collects biospecimens from adults to inform FDA's regulatory actions under the Family Smoking Prevention and Control Act. Cognitive interviews and focus groups are qualitative methods to assess how people interpret, process, retrieve, and respond to phrases, questions, response options, and product images that may be used in the development of the PATH Study's questionnaires and other materials. These methods have previously been used to help the PATH Study improve the comprehensibility of its materials for Study participants, and to increase efficiencies in data collection and reduce duplication and its associated burden on participants and the public.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total annualized burden hours are 2,400.

Estimated Annualized Burden Hours

Activity Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Annual Burden Hours
Completing eligibility screener	Youth	1,200	1	10/60	200
	Adults	2,400	1	10/60	400
Examining concepts to be measured in PATH Study	Adults	200	1	90/60	300

Examining assent forms for participation in PATH Study	Youth	200	1	90/60	300
Examining consent forms for participation in PATH Study	Adults	200	1	90/60	300
Examining other forms and materials to support PATH Study data collection	Adults	200	1	90/60	300
Examining PATH Study questionnaires	Youth	100	1	90/60	150
	Adults	300	1	90/60	450

Dated: June 23, 2015**.**

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Project Clearance Liaison

NIDA, NIH

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