a disability, please contact Lee L. Zwanziger at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 19, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–28462 Filed 11–23–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Methodological Studies for the Population Assessment of Tobacco and Health (PATH) Study

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 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.

Proposed Collection: Title: Methodological Studies for Population Assessment of Tobacco and Health (PATH) Study. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The PATH study will establish a population-based framework for monitoring and evaluating the behavioral and health impacts of regulatory provisions implemented as part of the Family Smoking Prevention and Tobacco Control Act (FSPTCA) by the Food and Drug Administration (FDA). NIDA is requesting generic approval from OMB for methodological studies to improve the PATH study instrumentation and data collection procedures. These methodological studies will support ongoing assessment and refinement of the PATH study's design, and highlight ways to improve study implementation and techniques for retention and followup. Data collection methods to be used in these methodological studies include: in-person and telephone surveys; web and smartphone/mobile phone surveys; and focus group and individual in-depth qualitative interviews. Biospecimens may also be collected from adults.

Frequency of Response: Annual [As needed on an on-going and concurrent basis]. *Affected Public:* Individuals. *Type of Respondents:* Youth (ages 12–17) and Adults (ages 18+). *Annual Reporting Burden:* See Table 1. The annualized cost to respondents is estimated at: $227,562. There are no capital, operating or maintenance costs.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN SUMMARY—METHODOLOGICAL STUDIES FOR THE PATH STUDY

Data collection activity	Type of respondent	Number of respondents	Responses per respondent	Hours per response	Annual hour burden
In-person and telephone surveys	Adults	3,000	1	1½	4,500
	Youth	2,000	1	1½	3,000
Web and smartphone/mobile phone surveys	Adults	3,000	1	1½	4,500
	Youth	2,000	1	1½	3,000
Focus groups and individual in-depth qualitative interviews	Adults	800	1	2	1,600
	Youth	800	1	2	1,600
Total		11,600			18,200

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.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans 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; Rockville, MD 20852, or call non-toll free number 301–443–8755 or email your request, including your address to: *PATHprojectofficer@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 14, 2012.

Glenda J. Conroy,

Executive Officer (OM Director), NIDA.

[FR Doc. 2012–28575 Filed 11–23–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Report of the Evidence-Based Methodology Workshop on Polycystic Ovary Syndrome—Request for Comments

SUMMARY: The National Institutes of Health (NIH) will place in the docket for public review and comment a report resulting from the NIH Evidence-Based Methodology Workshop on Polycystic Ovary Syndrome, to be held December