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

3–5, 2012. The purpose of the report is to summarize the workshop and identify future research priorities. The report will be available online beginning December 7, 2012, at *http://prevention.nih.gov/workshops/2012/pcos/default.aspx*.

DATES: Comments on the report will be accepted from December 7, 2012, to January 4, 2013.

ADDRESSES: Written comments must be postmarked by January 4, 2013, and should be sent to the NIH Office of Disease Prevention, ATTN: Paris A. Watson, 6100 Executive Boulevard, Suite 2B03, Bethesda, Maryland 20892. Email comments should be sent to *prevention@mail.nih.gov* by January 4, 2013.

FOR FURTHER INFORMATION CONTACT: To request more information, please contact Paris A. Watson at 301–496–6615 or *prevention@mail.nih.gov*.

SUPPLEMENTARY INFORMATION: Polycystic ovary syndrome (PCOS) is a common hormone disorder that affects approximately 5 million reproductive-aged women in the United States. Women with PCOS have difficulty becoming pregnant (i.e., are infertile) due to hormone imbalances that cause or result from altered development of ovarian follicles. One such imbalance is high blood levels of androgens, which can come from both the ovaries and adrenal gland. Other organ systems that are affected by PCOS include the pancreas, liver, muscle, blood vasculature, and fat.

In addition to fertility impairment, other common symptoms of PCOS include:

- Irregular or no menstrual periods (for women of reproductive age)
- Acne
- Weight gain
- Excess hair growth on the face and body
- Thinning scalp hair
- Ovarian cysts.

Women with PCOS are often resistant to the biological effects of insulin and, as a consequence, may have high insulin levels. As such, women with PCOS are at risk for type 2 diabetes, high cholesterol, and high blood pressure. Obesity also appears to worsen the condition. Costs to the U.S. health care system to identify and manage PCOS are approximately $4 billion annually; however, this estimate does not include treatment of the serious conditions associated with PCOS.

For most of the 20th century, PCOS was a poorly understood condition. In 1990, the NIH held a conference on PCOS to create both a working definition of the disorder and diagnostic criteria. The outcome of this conference, the *NIH Criteria,* served as a standard for researchers and clinicians for more than a decade. In 2003, a consensus workshop in Rotterdam developed new diagnostic criteria, the *Rotterdam Criteria*. The 2012 NIH Evidence-Based Methodology Workshop on PCOS seeks to clarify:

- The benefits and drawbacks of using the *Rotterdam Criteria;*
- The condition's causes, predictors, and long-term consequences;
- The optimal prevention and treatment strategies.

The NIH workshop is sponsored by the Office of Disease Prevention and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development. A multidisciplinary steering committee developed the workshop agenda. The NIH Library created an extensive, descriptive bibliography on PCOS to facilitate workshop discussion. During the two-and-one-half-day workshop, invited experts will discuss the body of evidence and attendees will have opportunities to provide comments during open discussion periods. After weighing the evidence, an unbiased, independent panel will prepare a report that summarizes the workshop and identifies future research priorities.

The report will be available online beginning December 7, 2012, at *http://prevention.nih.gov/workshops/2012/pcos/default.aspx*.

Dated: November 16, 2012.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2012–28608 Filed 11–23–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2011–0619]

Mechanisms of Compliance With United States Citizenship Requirements for the Ownership of Vessels Eligible To Engage in Restricted Trades by Publicly Traded Companies

AGENCY: Coast Guard, DHS.

ACTION: Notice; response to comments.

SUMMARY: As part of its January 2011 report on a Coast Guard investigation into the citizenship of owners of a publicly traded company, the National Vessel Documentation Center recommended requesting comments and information on the various measures that publicly traded companies employ to comply with the statutory requirement that at least 75 percent of the ownership of companies that operate vessels engaged in the coastwise trade be vested in U.S. citizens. On November 3, 2011, the Coast Guard published a notice in the **Federal Register** seeking those comments and that information. The Coast Guard read the written submissions and listened to oral comments generated by that notice and issues today's notice to inform industry and the public on how the Coast Guard plans to exercise its discretion in enforcing the referenced U.S. citizen ownership requirement.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this notice as being available in the docket, are part of docket USCG–2011–0619 and are available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet by going to *http://www.regulations.gov,* inserting USCG–2011–0619 in the ''Search'' box, and then clicking ''Search.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Mr. Douglas Cameron, United States Coast Guard, National Vessel Documentation Center; telephone 304–271–2506, email *Douglas.G.Cameron@uscg.mil*. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: On November 3, 2011, the Coast Guard published a notice in the **Federal Register** (76 FR 68203) (''2011 notice'') requesting comments and information on the various measures that publicly traded companies employ in order to comply with the requirement in 46 U.S.C. 50501 that at least 75 percent of the ownership of companies that operate vessels engaged in the coastwise trade be vested in U.S. citizens. The 2011 notice was published because of a recommendation in a January 12, 2011, Coast Guard report of an investigation into the citizenship of Trico Marine Services, Inc. (''Trico Report''). A copy of this report has been placed in the docket and is also available via *http://www.uscg.mil/hq/cg5/nvdc/* (under the Latest News tab). The Coast Guard solicited the following information in the 2011 notice (emphasis added):