priorities. CDRH's experience in guidance development has shown that there are many reasons that CDRH staff may not complete the entire agenda of guidance documents it undertakes. Staff are frequently diverted from guidance development to other priority activities. In addition, at any time new issues may arise to be addressed in guidance that could not have been anticipated at the time the annual list is generated. These issues may involve newly identified public health issues as well as special control documents that are necessary for the classification of de novo devices.

FDA anticipates that feedback from stakeholders, including draft language for guidance documents, will allow CDRH to better prioritize and more efficiently draft guidances that will be useful to industry and other stakeholders. FDA intends to update the list each year.

FDA invites interested persons to submit comments on any or all of the guidance documents on the lists. FDA has established a docket where comments on the FY 2013 lists, draft language for guidance documents on those topics, suggestions for new or different guidances, and relative priority of guidance documents may be submitted (see **ADDRESSES**). FDA believes this docket is an important tool for receiving information from interested parties and for sharing this information with the public. Similar information about planned guidance development is included in the annual Agency-wide notice issued under its good guidance practices (21 CFR 10.115(f)(5)). The CDRH lists, however, will be focused exclusively on device-related guidances and will be made available on FDA's Web site at the beginning of each fiscal year from 2013 to 2017. To access the lists of guidance documents CDRH is intending to publish in FY 2013, visit FDA's Web site *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm321367.htm*

## II. Request for Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: November 7, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012–28539 Filed 11–23–12; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–N–0001]**

### Risk Communication Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Risk Communication Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on February 12, 2013, from 8 a.m. to 3 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

*Contact Person:* Lee L. Zwanziger, Risk Communication Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3278, Silver Spring, MD 20993, 301–796–9151, FAX: 301–847–8611, email: *RCAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* On February 12, 2013, the Committee will discuss general factors in risk communication about FDA regulated products, including approaches to avoid message fatigue and related communication barriers such as prevention or warning fatigue or inaccurate risk perception.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 28, 2013. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11:30 a.m. on February 12, 2013. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 17, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 18, 2013. Interested persons can also log on to *https://collaboration.fda.gov/rcac/* to hear and see the proceedings.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to

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