

Dated: September 25, 2012.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0001]

#### Request for Nominations for Voting Members on a Public Advisory Committee; Tobacco Products Scientific Advisory Committee

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Tobacco Products Scientific Advisory Committee, Office of Science, Center for Tobacco Products.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups.

**DATES:** Nominations received on or before December 4, 2012, will be given first consideration for membership on the Tobacco Products Scientific Advisory Committee. Nominations received after December 4, 2012, will be considered for nomination to the committee as later vacancies occur.

**ADDRESSES:** All nominations for membership should be sent electronically to [cv@oc.fda.gov](mailto:cv@oc.fda.gov) or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002.

**FOR FURTHER INFORMATION CONTACT:** *Regarding all nomination questions for membership, the primary contact is:* Caryn Cohen, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1-877-287-1373 (choose Option 4), FAX: 240-276-3655, [TPSAC@fda.hhs.gov](mailto:TPSAC@fda.hhs.gov).

Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

**SUPPLEMENTARY INFORMATION:** FDA is requesting nomination for voting

members on the Tobacco Products Scientific Advisory Committee. Elsewhere in this issue of the **Federal Register**, FDA is publishing a separate document announcing the Request for Notification for Nonvoting Members on the Tobacco Products Scientific Advisory Committee.

#### I. General Description of the Committee Duties

The Tobacco Products Scientific Advisory Committee advises the Commissioner of Food and Drugs (the Commissioner) or designee in discharging responsibilities as they relate to the regulation of tobacco products. The Committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information and recommendations to the Commissioner.

#### II. Criteria for Voting Members

The Committee shall consist of 12 members including the Chair. Members and the Chair are selected by the Commissioner or designee from among individuals knowledgeable in the fields of medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The Committee shall include nine technically qualified voting members, selected by the Commissioner or designee. The nine voting members shall be physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty.

In addition to the voting members, the committee shall include three nonvoting members who are identified with industry interests. These members shall include one representative of the tobacco manufacturing industry, one representative of the interests of tobacco growers, and one representative of the interests of the small business tobacco manufacturing industry.

#### III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the advisory committee. Self-nominations are also accepted. Nominations must include a current, complete resume or curriculum vitae for each nominee, including current business address and/or home address, telephone number, and email address if available. Nominations must also

specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: September 24, 2012.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2012-24476 Filed 10-3-12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities; Proposed Collection; Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Officer at (301) 443-1984.

*Comments are invited on:* (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

*Proposed Project:* HRSA National Environmental Policy Act (NEPA) Environmental Information and

Documentation (EID) (OMB No. 0915–0324) Revision.

HRSA is requesting extension of the approval for the Environmental Information and Documentation (EID) checklist which consists of information that the agency is required to obtain to

comply with the National Environmental Policy Act of 1969 (NEPA). NEPA establishes the federal government’s national policy for protection of the environment. HRSA has developed the EID for applicants of funding that would potentially impact

the environment and to ensure that their decision-making processes are consistent with NEPA. Applicants must provide information and assurance of compliance with NEPA on the EID checklist. The estimated annual burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
NEPA EID Checklist .....	2,734	1	2,734	1	2,734
Total .....	2,734	1	2,734	1	2,734

Email comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Reports Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: October 2, 2012.

**Bahar Niakan,**

Director, Division of Policy and Information Coordination.

[FR Doc. 2012–24626 Filed 10–4–12; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Request for Comments Under the Paperwork Reduction Act, Section 3506**

**AGENCY:** National Institutes of Health (NIH), HHS.

**ACTION:** Request for comments.

**SUMMARY:** The National Institutes of Health (NIH), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Section 3506.

*Proposed Collection: Title:* National Institutes of Health Information Collection Forms to Support Genomic Data Sharing for Research Purposes; *Type of Information Collection Request:* New; *Need and Use of Information Collection:* The NIH mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to

enhance health, lengthen life, and reduce the burdens of illness and disability. The sharing of research data supports this mission and is essential to facilitate the translation of research results into knowledge, products, practices, and procedures that improve human health.

By enabling secondary research questions to be addressed, data sharing maximizes the public benefit achieved through research investments. NIH’s *Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)* was established to enable the full value of GWAS data to be realized. GWAS data are maintained in a central data repository, the database of Genotypes and Phenotypes (dbGaP), which is administered by the National Center for Biotechnology Information (NCBI), part of the National Library of Medicine at NIH.

As stipulated in the NIH GWAS policy, all principal investigators (PIs) who receive NIH funding to conduct genomic research are expected to register studies with genomic data in dbGaP. The nature of the genomic, phenotypic, and other associated data generated through large-scale human genomic studies requires responsible stewardship throughout research and data sharing activities. Since the data being collected and shared are from human research participants, the protection of participant interests is paramount. PIs submitting data to dbGaP must describe any limitations on sharing the data, as defined in the informed consent provided by the participants from whom the data were originally collected. PIs must also provide basic study information such as the type of data that will be submitted to dbGaP and a description of the study.

Researchers interested in using dbGaP data for secondary research must submit a request through dbGaP and be granted permission from the relevant NIH Data Access Committees to access the data. As part of the request process, researchers must provide information such as a description of the proposed research use of the dbGaP datasets, a data security plan, and a Data Use Certification, in which the researcher agrees to the terms and conditions for use of the data. NIH has developed online forms, which will be available through dbGaP, in an effort to reduce the burden for researchers to complete the study registration, data submission, and data access processes.

*Frequency of Response:* As necessary.

*Description of Respondents:* PIs and senior officials from their institutions.

*Estimate of Burden:* The burden associated with this information collection is calculated in two parts: (1) The burden associated with registering genomic studies and submitting data to dbGaP and (2) the burden associated with applying for genomic data in dbGaP. The annual reporting burden for study registration and data submission is as follows: *Estimated Number of Respondents:* 100; *Estimated Number of Responses per Respondent:* 1; and *Estimated Total Annual Burden Hours Requested:* 63. The annual cost to respondents is estimated at \$2,506. The annual reporting burden for applying for genomic data in dbGaP is as follows: *Estimated Number of Respondents:* 1,266; *Estimated Number of Responses per Respondent:* 2; and *Estimated Total Annual Burden Hours Requested:* 1,583. The annual cost to respondents is estimated at \$63,452. There are no capital, operating, or maintenance costs to the respondents.