

workshops regarding analysis of tobacco products.

## II. Workshop Topics for Discussion

FDA will explore all or some of the following topics during this scientific workshop:

### 1. Availability, Manufacture, and Characterization of Tobacco Reference Products

A. Discuss the current availability of tobacco reference products for different types of tobacco products and what new products would be beneficial.

B. Discuss the types and blends of tobacco used in reference products. What additional blends or other product characteristics should be most applicable for all products, both those currently and those expected to be introduced on the market?

C. Describe the storage conditions for tobacco reference products to ensure shelf life. Please provide data that shows product changes under different storage conditions. What storage conditions are most critical in maintaining product integrity? What precautions should be taken to ensure product integrity?

D. Discuss the stability of the tobacco reference products and methods used to verify product stability. What precautions are taken to maximize product stability? What product characteristics are most stable and which are least stable?

E. Describe any ongoing work to develop tobacco reference products that are not currently available for laboratory use. Discuss considerations made when determining the need and developing a new tobacco reference product.

### 2. Uses of Reference Products During Analysis of Tobacco Products

A. Discuss the physical and chemical measurements performed on tobacco reference products during analysis of tobacco products. Please provide data. How are reference products used in research and manufacturing?

B. Discuss the advantages and disadvantages of using one or multiple tobacco reference products when performing analysis of a given tobacco product type.

C. Discuss the procedures used when transitioning from using one tobacco reference product to using another tobacco reference product for the same tobacco product type to ensure long-term consistency in findings.

D. Discuss the policies, procedures, and frequency related to discarding data for reference products due to unacceptable analytical results.

E. Discuss the policies and procedures used in research and manufacturing when no tobacco reference product is available for a specific type of tobacco product. Is there a policy of using a similar product when the specific reference product is not available? What considerations are applied?

F. Describe characteristics of a tobacco reference product that would provide advantages or disadvantages over another.

### 3. Variability Observed in Measurements of Tobacco Reference Products

A. Provide data that address the variability that exists in the chemical measures of a reference product analyzed within the same laboratory. Describe how measures compare between different laboratories.

B. Provide data that address the variability that exists in the physical measures of a reference product analyzed within the same laboratory. Describe how measures compare between different laboratories.

C. Describe any other factors that affect the variability of a tobacco reference product when analyzed using analytical measurements.

D. Discuss the procedures or methods that have been used or may be used to reduce the tobacco reference product variability.

### 4. Methods Suitable for Measuring the Following in Smoked and Smokeless Tobacco Products: pH, Tobacco-Specific Nitrosamines, Polycyclic Aromatic Hydrocarbons, Carbon Monoxide, and Metals

A. Discuss the sample preparation or extraction methods for measuring the analytes.

B. Discuss the analytical methodologies (gas chromatography, thermal energy analyzer, liquid chromatography, mass spectrometry, etc.) used for quantifying analytes.

C. Discuss the statistical or other mathematical procedures for quantification.

D. Discuss the availability and use of internal reference standards to quantify the analytes.

E. Discuss the approaches and testing methods which are intended to combine measuring of multiple analytes within the same class of constituents into a single analysis. Particularly discuss the benefits in reference to sample throughput and the loss in terms of sensitivity, selectivity, or other analytical terms of reference.

F. Discuss the approaches and testing methods which are intended to measure analytes across different classes of

constituents. Particularly discuss the benefits in reference to sample throughput and the loss in terms of sensitivity, selectivity, or other analytical terms of reference.

## III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: March 8, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2012-6037 Filed 3-12-12; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR11-350 Research Using Biosamples from Selected Type 1 Diabetes Clinical Studies (DP3).

*Date:* April 2, 2012.

*Time:* 2:30 p.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes Of Health,

Room 759, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, 301-594-2242, [jerkinsa@nidddk.nih.gov](mailto:jerkinsa@nidddk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Collaborative Interdisciplinary Team Science R24-6.

*Date:* April 11, 2012.

*Time:* 2 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Lakshmanan Sankaran, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes Of Health, Room 755, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7799, [ls38z@nih.gov](mailto:ls38z@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 7, 2012.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2012-6019 Filed 3-12-12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Allergy and Infectious Diseases Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Application (P01).

*Date:* March 20, 2012.

*Time:* 11 a.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive,

Bethesda, MD 20817, (Telephone Conference Call).

*Contact Person:* Jane K. Battles, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, Room 3128, Bethesda, MD 20892-7616, 301-451-2744, [battlesja@mail.nih.gov](mailto:battlesja@mail.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01).

*Date:* April 3, 2012.

*Time:* 11 a.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

*Contact Person:* Brenda Lange-Gustafson, Ph.D., Scientific Review Officer, NIAID/NIH/DHHS, Scientific Review Program, Room 3122, 6700-B Rockledge Drive, MSC-7616, Bethesda, MD 20892-7616, 301-451-3684, [bgustafson@niaid.nih.gov](mailto:bgustafson@niaid.nih.gov).

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel; "NIH Support for Conferences and Scientific Meetings (Parent R13/U13)"

*Date:* April 9-11, 2012.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817, (Virtual Meeting).

*Contact Person:* Jay R. Radke, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, Room 2217, 6700B Rockledge Drive MDS-7616, Bethesda, MD 20892-7616, 301-496-2550, [jay.radke@nih.gov](mailto:jay.radke@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 7, 2012.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2012-6020 Filed 3-12-12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### NATIONAL INSTITUTES OF HEALTH

#### National Eye Institute Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the

provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Eye Institute Special Emphasis Panel; Vision Research Grant Applications.

*Date:* April 2, 2012.

*Time:* 8:30 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Daniel R. Kenshalo, Ph.D., Scientific Review Officer, Division of Extramural Research, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, MSC 9300, 301-451-2020, [kenshalod@nei.nih.gov](mailto:kenshalod@nei.nih.gov).

*Name of Committee:* National Eye Institute Special Emphasis Panel; Posterior Eye Disease, Epidemiology and Genetics.

*Date:* April 17, 2012.

*Time:* 3 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Eye Institute, National Institutes of Health, 5635 Fishers Lane (Telephone Conference Call).

*Contact Person:* Anne E. Schaffner, Ph.D., Chief, Scientific Review Officer, Division of Extramural Research, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, MSC 9300, 301-451-2020, [aes@nei.nih.gov](mailto:aes@nei.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: March 7, 2012.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Dental & Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute of Dental and Craniofacial Research.

The meeting will be closed to the public as indicated below in accordance