

4952, FAX: 214-253-4970, e-mail: [david.arvelo@fda.hhs.gov](mailto:david.arvelo@fda.hhs.gov).

For information on accommodation options, contact conference coordinator Karen Smith or Andrea Graves at the Robert M. Kerr Food & Agricultural Products Center, Oklahoma State University, 148 FAPC, Stillwater, OK 74078-6055, 405-744-6071, FAX: 405-744-6313, or e-mail: [karenl.smith@okstate.edu](mailto:karenl.smith@okstate.edu) or [andrea.graves@okstate.edu](mailto:andrea.graves@okstate.edu). More information is also available online at <http://www.fapc.biz/fooddefense.html>. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

**Registration:** You are encouraged to register by October 21, 2011. The workshop has a \$150 registration fee to cover the cost of facilities, materials, speakers, and breaks. Seats are limited; please submit your registration as soon as possible. The workshop will be filled in order of receipt of registration. Those accepted into the workshop will receive confirmation. Registration will close after the workshop is filled. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the public workshop beginning at 8 a.m. The cost of registration at the site is \$200 payable to FAPC. There is no registration fee for FDA employees.

If you need special accommodations due to a disability, please contact Karen Smith (see *Contact*) at least 7 days in advance.

**Registration Form Instructions:** To register, please complete the online registration form at <http://www.fapc.biz/fooddefense.html>.

**Transcripts:** Transcripts of the public workshop will not be available due to the format of this workshop. Course handouts may be requested after the date of the public workshop through the contact persons (see *Contact*) at cost plus shipping.

**SUPPLEMENTARY INFORMATION:** This public workshop is being held in response to the large volume of food defense inquiries from food manufacturers originating from the area covered by the FDA Dallas District Office. The SWRO presents this workshop to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is consistent with the purposes of the Southwest Regional

Small Business Representative Program, which are in part to respond to industry inquiries, develop educational materials, and sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's regulations and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), as outreach activities by government agencies to small businesses.

The goal of this public workshop is to present information that will enable regulated industry to better comply with the regulations authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and to better understand FDA's food defense guidance documents, especially in light of growing concerns about food protection. Information that FDA presents will be based on Agency position as articulated through regulation, guidance, and information previously made available to the public. Topics to be discussed at the workshop (both by FDA and non-FDA speakers) include: (1) Food defense awareness and definitions, (2) FDA food defense tools such as ALERT and Employees FIRST, (3) regulations issued under the Bioterrorism Act, (4) food defense guidance documents, (5) investigating food-related incidents effectively, (6) physical plant security, (7) crisis management, and other related topics. For more information, please visit <http://www.fapc.biz/fooddefense.html>. FDA expects that participation in this public workshop will provide regulated industry with greater understanding of the Agency's regulatory and policy perspectives on food protection, increase compliance with FDA regulations, and heighten food defense awareness.

Dated: September 23, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0002]

#### Request for Notification From Industry Organizations Interested in Participating in the Selection Process and Request for Nominations for a Nonvoting Industry Representative on the Vaccines and Biological Products Advisory Committee

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Vaccines and Related Biological Products Advisory Committee for the Center for Biologics Evaluation and Research (CBER) notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative to serve the Vaccines and Related Biological Products Advisory Committee. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nomination will be accepted for current vacancies effective with this notice.

**DATES:** Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to the FDA by October 31, 2011, for the vacancy listed in this document. Concurrently, nomination materials for prospective candidates should be sent to FDA by October 31, 2011.

**ADDRESSES:** All letters of interest and nominations should be submitted in writing to Donald Jehn (see **FOR FURTHER INFORMATION CONTACT**).

**FOR FURTHER INFORMATION CONTACT:** Donald Jehn, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0314, FAX: 301-827-0294, e-mail: [donald.jehn@fda.hhs.gov](mailto:donald.jehn@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The Agency intends to add a nonvoting industry representative on the CBEP Advisory Committee.

#### I. Vaccines and Related Biological Products Advisory Committee

The Vaccines and Related Biological Products Advisory Committee (the Committee) advises the Commissioner

of Food and Drugs (the Commissioner) or designee in discharging responsibilities as they relate to the regulation of vaccines and related biological products. Members are asked to provide their expert scientific and technical advice to FDA to help make sound decisions on the safety, effectiveness, and appropriate use, of vaccines and related biological products.

## II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT and DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the Committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

## III. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative (for the roles specified in this document). Nominations must include a current resume or curriculum vitae of the nominee including current business address and/or home address, telephone number, email address if available, and the role for which the individual is being nominated. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA has a special interest in ensuring that women, minority groups, individuals with physical disabilities, and small businesses are adequately represented on its advisory committees, and therefore, encourages nominations for appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5

U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: September 23, 2011.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2011-25120 Filed 9-28-11; 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 Meeting

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 meeting.

The meeting 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; Digestive Diseases Core Centers.

*Date:* December 2, 2011.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

*Contact Person:*

Maria E. Davila-Bloom, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes Of Health, Room 758, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7637, [davila-bloomm@extra.nidk.nih.gov](mailto:davila-bloomm@extra.nidk.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: September 23, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; 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:* Center for Scientific Review Special Emphasis Panel, Surgical Sciences and Bioengineering.

*Date:* October 20, 2011.

*Time:* 12 p.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Malgorzata Klosek, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4188, MSC 7849, Bethesda, MD 20892, (301) 435-2211, [klosekm@csr.nih.gov](mailto:klosekm@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Small Business: Diabetes, Obesity and Reproductive Sciences.

*Date:* October 25-26, 2011.

*Time:* 11:30 a.m. to 2 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Krish Krishnan, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, (301) 435-1041, [krishnak@csr.nih.gov](mailto:krishnak@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Fellowship: Genes, Genomes, and Genetics.

*Date:* October 26, 2011.

*Time:* 11 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Allen Barlow Richon, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7892, Bethesda, MD 20892, 301-435-1024, [allen.richon@nih.hhs.gov](mailto:allen.richon@nih.hhs.gov).