

Time: 8 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Crystal Gateway Marriott, 1700 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: Keith A. Mintzer, PhD, Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7186, Bethesda, MD 20892-7924, 301-435-0280, mintzerk@nhlbi.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Center for Gene Transfer.

Date:

Date: June 20, 2011.

Time: 12 p.m. to 3 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: William J Johnson, PhD, Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7178, Bethesda, MD 20892-7924, 301-435-0725, johnsonwj@nhlbi.nih.gov (Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 17, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-12630 Filed 5-20-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; 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 Center for Complementary and Alternative Medicine

Special Emphasis Panel; NCCAM Education Panel.

Date: June 23-24, 2011.

Time: 8 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Courtyard Gaithersburg Washingtonian Ctr, 204 Boardwalk Place, Gaithersburg, MD 20878.

Contact Person: Peter Kozel, PhD, Scientific Review Officer, NCCAM, 6707 Democracy Boulevard, SUITE 401, Bethesda, MD 20892-5475, 301-496-8004, kozelp@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: May 17, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-12640 Filed 5-20-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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 General Medical Sciences Initial Review Group, Biomedical Research and Research Training Review Subcommittee B.

Date: June 17, 2011.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Washington DC-Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Contact Person: Arthur L. Zachary, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN-18, Bethesda, MD 20892, 301-594-2886, zacharya@nigms.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and

Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: May 17, 2011.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-12639 Filed 5-20-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Call for Participation in Pillbox Patient-Safety Initiative

ACTION: Notice.

SUMMARY: The National Library of Medicine (NLM) invites the participation of manufacturers, including repackagers, and private label distributors of solid oral dosage form medications in the development of Pillbox, a publicly accessible online repository of digital images and descriptive information for solid oral dosage form medications. This project seeks to promote utilization of the SPLIMAGE element of the Food and Drug Administration (FDA) Structured Product Label (SPL) through development and use of imaging standards and methodologies. Through this Call for Participation, NLM seeks to evaluate the photography methodology and procedures it has developed for creating standardized high-resolution images of solid oral dosage form medications that are appropriate for inclusion in the SPL. Participating organizations will be invited to submit samples of their solid oral dosage form medications to NLM for imaging. Resulting image files will be provided to participants, who may choose to voluntarily include them in their subsequent SPL submissions to FDA. Image files that are voluntarily submitted to FDA as part of an SPL listing submission will be included in the publicly accessible, production version of Pillbox. This initiative is an important element of ongoing efforts to enhance patient safety, reduce adverse drug events, and improve the quality and availability of drug information.

SUPPLEMENTARY INFORMATION: NLM has established Pillbox, an initiative to enhance patient safety, by making available via a publicly accessible resource (<http://pillbox.nlm.nih.gov>) digital images and descriptive data of

solid oral dosage form medications (e.g., capsules and tablets, also referred to as "pills"). NLM intends to create a search system allowing patients, healthcare providers, and the public to identify and reference medications using the submitted images and related descriptive information. Such a resource is intended to have application in poison control, emergency response, disaster response, anti-counterfeiting, manufacturer compliance with Federal regulations, improved prescription filling accuracy, and reduction of medication errors and adverse drug events.

Images of tablets and capsules that are currently available to the public from various online resources are of varying quality. There exists no single, authoritative resource of high-quality images representative of prescription and non-prescription medications available in the United States from which a trustworthy resource such as Pillbox can be constructed. To remedy this situation, NLM, working with FDA, has developed a standardized methodology for creating digital images of solid oral dosage form medications. Presently, NLM is testing a demonstration/beta version of Pillbox that contains SPL information for listed solid oral dosage form medications and NLM-produced images for approximately 1,000 solid oral dosage form medications. Because these images are not part of the SPL and have not been verified by the manufacturer; the demonstration/beta version of Pillbox contains a disclaimer indicating that it is a demonstration system that is not intended for clinical use.

In order to test the imaging methodology in an operational setting and to begin developing a production version of Pillbox, NLM is offering, on a time-limited basis, to provide manufacturers, including repackagers, and private label distributors who send product samples to NLM, image files suitable for inclusion with their SPL files that are being submitted to FDA. Manufacturers, including repackagers, and private label distributors may voluntarily include this standardized image in the SPL file they submit to FDA as part of the drug listing process. If a firm includes the image with an SPL submission, that image will be included in the production version of Pillbox. The production version of Pillbox will only contain images that have been verified by manufactures, including repackagers, and private label distributors. When the production version of Pillbox is launched, the current demonstration/beta version will be taken offline from public access and

will only be used for agency research and development. NLM may also use the images it produces to populate the offline version of Pillbox to further agency research and development.

Photography Facility

NLM, in collaboration with FDA, has set up a photography laboratory at an FDA facility in Rockville, Maryland for the purpose of generating standardized images of representative solid oral dosage form medications for the duration of this project. This facility is registered with the Drug Enforcement Administration.

NLM will provide to manufacturers, including repackagers, and private label distributors, at no cost, an image suitable for submission to FDA as part of drug listing for any actively marketed solid oral dosage form medication that is sent to them. The image will encompass visible spectrum only. Ultra-violet and infrared images will not be captured.

No physical or chemical tests or assays of any nature will be performed on the submitted products. Once imaging is completed, the representative solid oral dosage form medications will be destroyed.

Photographs will be provided for the duration of the testing period, which is anticipated to continue through FY2012. The agency will provide information about further development of Pillbox, the production of SPL image files, and the standardized methodology for SPL images after completion of the testing period.

Participation

We invite manufacturers, including repackagers, and private label distributors of solid oral dosage form medications to voluntarily participate in this program.

Procedure for Submitting Applicable Packaged Products for Imaging

Manufacturers, including repackagers, and private label distributors of prescription and over-the-counter solid oral dosage form medications may submit products for imaging. The expiration date on the submitted products' packaging should be the longest available expiration date. Participants should:

1. Indicate to the agency their intent to participate in this program via e-mail to pillbox@mail.nih.gov. It is not necessary to provide any information related to products which will be submitted in this announcement of intent. This initial communication is strictly to express intent and to allow for resource allocation planning.

2. Select and ship the smallest volume stock package(s) totaling at least 8–10 representative solid oral dosage form medications (e.g., tablets, capsules) of the same drug product. In order to ensure the safety of facility staff and compliance with appropriate federal regulations please include the accompanying prescribing information.

- a. Consolidated shipments of multiple packages are permitted.

- b. If there is an undue financial burden associated with providing the smallest volume stock package, please contact NLM via e-mail to pillbox@mail.nih.gov.

3. Provide contact information for the person(s) submitting the solid oral dosage form medications and receiving the final images. Contact information should include:

- a. Firm's name and address.

- b. Name, e-mail address, and telephone number of the person submitting the representative solid oral dosage form medications.

- c. Name, e-mail address, and telephone number of the person who is responsible for receiving the final images of the representative solid oral dosage form medications.

4. Send the representative solid oral dosage form medications to:

- a. NLM PILLBOX IMAGING PROJECT, Attn: Staff Pharmacist, 2094 Gaither Rd., Suite 240, Room 245, Rockville, MD 20850.

The final image file will be sent to the specified e-mail address of the person who is responsible for receiving the final image. The manufacturer, repackager, or private label distributor may voluntarily include the provided image in an SPL drug listing submission to FDA, in the SPLIMAGE data element. Images submitted as part of the SPL will be included in the production version of Pillbox.

Partnership Acknowledgment

Manufacturers, including repackagers, and private label distributors who participate in this process will be acknowledged on the Pillbox Web site and in other communications about the project.

FOR FURTHER INFORMATION CONTACT: Any question regarding this process or the Pillbox initiative, including alternative methods for receiving the images, should be sent to pillbox@mail.nih.gov. Any questions regarding submission of the file to FDA should be sent to spl@fda.hhs.gov.

Dated: May 16, 2011.

Todd Danielson,

Executive Officer, National Library of Medicine, National Institutes of Health.

[FR Doc. 2011-12629 Filed 5-20-11; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2011-0038]

The Critical Infrastructure Partnership Advisory Council (CIPAC)

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: Quarterly CIPAC membership update.

SUMMARY: The Department of Homeland Security (DHS) announced the establishment of the Critical Infrastructure Partnership Advisory Council (CIPAC) by notice published in the **Federal Register** Notice (71 FR 14930-14933) dated March 24, 2006. That notice identified the purpose of CIPAC as well as its membership. This notice provides: (i) The quarterly CIPAC membership update; (ii) instructions on how the public can obtain the CIPAC membership roster and other information on the Council; and, (iii) information on recently completed CIPAC meetings.

FOR FURTHER INFORMATION CONTACT: Nancy J. Wong, Director, Partnership Programs and Information Sharing Office, Partnership and Outreach Division, Office of Infrastructure Protection, National Protection and Programs Directorate, U.S. Department of Homeland Security, 245 Murray Lane, Mail Stop 0607, Arlington, VA 20598-0607, by telephone (703) 235-3999 or via e-mail at CIPAC@dhs.gov.

Responsible DHS Official: Nancy J. Wong, Director Partnership Programs and Information Sharing Office, Partnership and Outreach Division, Office of Infrastructure Protection, National Protection and Programs Directorate, U.S. Department of Homeland Security, 245 Murray Lane, Mail Stop 0607, Arlington, VA 20598-0607, by telephone (703) 235-3999 or via e-mail at CIPAC@dhs.gov.

SUPPLEMENTARY INFORMATION:

Purpose and Activity: The CIPAC facilitates interaction between government officials and representatives of the community of owners and/or operators for each of the critical infrastructure sectors defined by Homeland Security Presidential Directive 7 (HSPD-7) and identified in the National Infrastructure Protection

Plan (NIPP). The scope of activities covered by the CIPAC includes planning; coordinating among government and critical infrastructure owner/operator security partners; implementing security program initiatives; conducting operational activities related to critical infrastructure protection security measures, incident response, recovery, infrastructure resilience, reconstituting critical infrastructure assets and systems for both man-made as well as naturally occurring events; and sharing threat, vulnerability, risk mitigation, and infrastructure continuity information.

Organizational Structure: CIPAC members are organized into eighteen (18) critical infrastructure sectors. Within all of the sectors containing critical infrastructure owners/operators, there generally exists a Sector Coordinating Council (SCC) that includes critical infrastructure owners and/or operators or their representative trade associations. Each of the sectors also has a Government Coordinating Council (GCC) whose membership includes a lead Federal agency that is defined as the Sector Specific Agency (SSA), and all relevant Federal, state, local, tribal, and/or territorial government agencies (or their representative bodies) whose mission interests also involve the scope of the CIPAC activities for that particular sector.

CIPAC Membership: CIPAC Membership may include:

- (i) Critical infrastructure owner and/or operator members of an SCC;
- (ii) Trade association members who are members of an SCC representing the interests of critical infrastructure owners and/or operators;
- (iii) Each sector's Government Coordinating Council (GCC) members; and,
- (iv) State, local, tribal, and territorial governmental officials comprising the DHS State, Local, Tribal, and Territorial GCC.

CIPAC Membership Roster and Council Information: The current roster of CIPAC membership is published on the CIPAC Web site (<http://www.dhs.gov/cipac>) and is updated as the CIPAC membership changes. Members of the public may visit the CIPAC Web site at any time to obtain current CIPAC membership as well as the current and historic list of CIPAC meetings and agendas.

Dated: May 13, 2011.

Nancy Wong,

Designated Federal Officer for the CIPAC.

[FR Doc. 2011-12615 Filed 5-20-11; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-1976-DR; Docket ID FEMA-2011-0001]

Kentucky; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the Commonwealth of Kentucky (FEMA-1976-DR), dated May 4, 2011, and related determinations.

DATES: *Effective Date:* May 10, 2011.

FOR FURTHER INFORMATION CONTACT:

Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the Commonwealth of Kentucky is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of May 4, 2011.

Bath, Green, Lewis, Mason, Pendleton, and Spencer Counties for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2011-12597 Filed 5-20-11; 8:45 am]

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