

Development, Evaluation, and Establishment of Specifications.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032; the collections of information in section 512(n)(1) of the FD&C Act (21 U.S.C. 360k) have been approved under OMB control number 0910–0669.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: January 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–00822 Filed 1–15–16; 8:45 am]

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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; Member Conflict: Auditory Neuroscience.

Date: February 2–3, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: John Bishop, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7844, Bethesda, MD 20892, (301) 408–9664, bishopj@csr.nih.gov.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Biomedical Computing and Health Informatics Study Section.

Date: February 5, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Mayflower Park Hotel, 405 Olive Way, Seattle, WA 98101.

Contact Person: Peter J. Kozel, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, Bethesda, MD 20892, 301–435–1116, kozelp@mail.nih.gov.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Instrumentation and Systems Development Study Section.

Date: February 10–11, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Best Western Tuscan Inn, 425 North Point Street, San Francisco, CA 94133.

Contact Person: Kathryn Kalasinsky, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5158 MSC 7806, Bethesda, MD 20892, 301–402–1074, kalasinskyks@mail.nih.gov.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Surgery, Anesthesiology and Trauma Study Section.

Date: February 10–11, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton San Diego Mission Valley, 901 Camino Del Rio South, San Diego, CA 92108.

Contact Person: Weihua Luo, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5114, MSC 7854, Bethesda, MD 20892, (301) 435–1170, luow@csr.nih.gov.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Motor Function, Speech and Rehabilitation Study Section.

Date: February 11–12, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Pier 2620 Hotel, 2620 Jones Street, San Francisco, CA 94133.

Contact Person: Biao Tian, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, MSC 7848, Bethesda, MD 20892, 301–402–4411, tianbi@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR13–213: Outcome Measures for Use in Treatment Trials for Individuals with Intellectual and Developmental Disabilities.

Date: February 11, 2016.

Time: 8:00 a.m. to 11:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Jane A. Doussard-Roosevelt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 435–4445, doussarj@csr.nih.gov.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Social Psychology, Personality and Interpersonal Processes Study Section.

Date: February 11–12, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westgate Hotel, 1055 Second Avenue, San Diego, CA 92101.

Contact Person: Marc Boulay, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, MSC 7808, Bethesda, MD 20892, (301) 300–6541, boulaymg@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Nursing and Related Clinical Sciences Overflow.

Date: February 11–12, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The St. Regis Washington DC, 923 16th Street N.W., Washington, DC 20006.

Contact Person: Martha L. Hare, Ph.D., RN, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3154, Bethesda, MD 20892, (301) 451–8504, harem@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR13–137: Bioengineering Research.

Date: February 11, 2016.

Time: 8:00 a.m. to 9:00 a.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Washington DC, Dupont Circle, 1143 New Hampshire Avenue N.W., Washington, DC 20037.

Contact Person: Yvonne Bennett, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5199, MSC 7846, Bethesda, MD 20892, 301–379–3793, bennetty@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Interventions to Prevent and Treat Addictions.

Date: February 11, 2016.

Time: 11:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Mayflower Hotel, 1127 Connecticut Avenue N.W., Washington, DC 20036.

Contact Person: Weijia Ni, Ph.D., Chief/Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3100, MSC 7808, Bethesda, MD 20892, (301) 594-3292, niw@csr.nih.gov.
(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 12, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-00794 Filed 1-15-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement of Requirements and Registration for “Pill Image Recognition Challenge”

Authority: 15 U.S.C. 3719

SUMMARY: The Pill Image Recognition Challenge is a National Institutes of Health (NIH) Challenge under the America COMPETES (Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science) Reauthorization Act of 2010 (Pub. L. 111-358). Through this Challenge, the National Library of Medicine (NLM), part of NIH, seeks algorithms and software to match images of prescription oral solid-dose pharmaceutical medications (pills, including capsules and tablets). The objective of the Challenge is the development and discovery of high-quality algorithms and software that rank how well consumer images of prescription pills match reference images of pills in the authoritative NLM RxIMAGE database. NLM may use all or part of any Challenge entry (*i.e.*, algorithm and software) to create a future software system and a future API (Application Programming Interface) for pill image recognition; the system will be freely usable and the API will be freely accessible.

DATES: NLM will make a set of consumer-quality images and a companion set of reference images publicly available on January 15, 2016.

The Challenge begins January 19, 2016.

Submission period: April 4, 2016 to May 31, 2016.

Judging period: June 6, 2016 to July 15, 2016.

Winners announced: August 1, 2016.

Submissions received by NLM after the submission period ends will not be considered. A submission is considered to meet the submission deadline if it is received by May 31, 2016, 5:00 p.m. EDT. While NLM plans to acknowledge receipt of each Challenge submission, the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. NLM will amend this **Federal Register** notice if the timeline or the rules for the Challenge are modified. In addition, NLM will notify registered Challenge participants by email of any amendments and will include the modified Challenge showing the changes.

ADDRESSES: Notifications of any amendment to this **Federal Register** notice and answers to frequently asked questions about it will be posted at <http://pir.nlm.nih.gov/challenge/notifications-and-FAQs>. Submissions must be mailed to: Pill Image Recognition Challenge, Computational Photography Project for Pill Identification (C3PI), National Library of Medicine, Building 38A, Room B1-N30, 8600 Rockville Pike, Bethesda, MD 20894.

FOR FURTHER INFORMATION CONTACT: Michael J. Ackerman, Ph.D. at (301) 402-4100 or PIR@nlm.nih.gov.

SUPPLEMENTARY INFORMATION:

The IC’s Statutory Authority To Conduct the Challenge

What has become today’s National Library of Medicine began in 1836 as a small collection of medical books and journals in the office of the U.S. Army Surgeon General. A 1956 act of Congress (Pub. L. 84-941) transferred the library to the Public Health Service and gave it its current name. That law authorizes NLM to “assist the advancement of medical and related sciences and to aid the dissemination and exchange of scientific and other information important to the progress of medicine and to the public health” and to “promote the use of computers and telecommunications by health professionals (including health professionals in rural areas) for the purpose of improving access to biomedical information for health care delivery and medical research.” In addition to its subject-matter authority, NLM is conducting this competition under the America COMPETES Reauthorization Act of 2010 (Pub. L. 111-358).

Subject of Challenge

Unidentified and misidentified prescription pills present challenges for patients and professionals. Unidentified pills can be found by family members, health professionals, educators, and law enforcement. The nine out of 10 U.S. citizens over age 65 who take more than one prescription pill can be prone to misidentifying those pills. Taking such pills can result in adverse drug events that affect health or cause death. To reduce such errors, any person should easily be able to confirm that a prescription pill or a refill is correct. For example, a person should be able to easily verify—or not—that a refill that has a different color, shape, or text imprinted on the pill is a different generic version of equivalent drugs he or she was already taking.

To help address these problems, the NLM Computational Photography Project for Pill Identification (C3PI) is developing infrastructure and tools for identifying prescription pills. The infrastructure includes photographs of such pills taken under laboratory lighting conditions, from a camera directly above the front and the back faces of the pill, and at high resolution. Specialized digital macro-photography techniques were then used to capture JPEG pill images. The NLM RxIMAGE database contains these high-quality images and associated pill data such as appearance (color, shape, size, text imprinted on the pill, etc.), ingredients, and identifiers such as its National Drug Code (NDC) [<http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm>]. RxIMAGE images and data are freely available. The freely accessible RxIMAGE API provides text-based search and retrieval of images and data from the RxIMAGE database. By contributing their algorithm and software, Challenge participants will take part in a broader NLM effort to develop a freely usable software system and a freely accessible API for image-based search and retrieval from a mobile device.

In a typical scenario for a future NLM mobile app, a person will download the app and use it to photograph a prescription pill, possibly under poor lighting conditions, from an angle, or at low resolution. The future app will communicate with the future pill image recognition software system, which may use all or part of any Challenge entry, to compare that photo to reference images in the RxIMAGE database, and will return one or more reference images that most likely match the photographed pill along with their associated pill data.