worldwide, without further payment or consideration.

HHS/CDC claims an irrevocable, royalty-free, non-exclusive worldwide license to use, copy for use, distribute, display publicly, create derivative works, and license others to do so for the purpose of the Dare to Prepare challenge and/or for the purpose of raising awareness for preparedness.

Compliance With Rules and Contacting Contest Winners

Finalists and the Contest Winners must comply with all terms and conditions of these Official Rules. Winning is contingent upon fulfilling all requirements herein. The finalists will be notified by email after points have been totaled and winners determined. Awards may be subject to Federal income taxes, and the Department of Health and Human Services will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

Privacy

When Contestants provide HHS/CDC with personal information by registering or filling out the submission form through the Challenge.gov Web site, that information is used to respond to Contestants in matters regarding their submission, announcements of entrants, finalists, and winners of the Contest. Information is not collected for commercial marketing. Winners are permitted to cite that they won this contest.

Liability

The Contestant/Submitter agrees to assume any and all risks and waive claims against the Federal Government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property (including any damage that may result from a virus, malware, etc. to HHS/CDC systems utilized to upload photos), revenue, or profits, whether direct, indirect, or consequential, arising from their participation in the competition, whether the injury, death, damage, or loss arises through negligence or otherwise. The Contestant/Submitter shall be liable for, and shall indemnify and hold harmless the Government against, all actions or claims for any claim, demand, judgment, or other allegation arising from alleged violation of an individual's trademark, copyright, or other legally protected interest in videos submitted to CDC.

Insurance

Contestants must obtain liability insurance or demonstrate financial responsibility in the amount of $0 for claims by: (1) A third party for death, bodily injury, or property damage, or loss resulting from an activity carried out in connection with participation in a competition, with the Federal Government named as an additional insured under the registered contestant's insurance policy and registered contestants agreeing to indemnify the Federal Government against third party claims for damages arising from or related to competition activities; and (2) the Federal Government for damage or loss to Government property resulting from such an activity. Contestants who are a group must obtain insurance or demonstrate financial responsibility for all members of the group.

General Conditions

HHS/CDC reserves the right to cancel, suspend, and/or modify the Contest, or any part of it, for any reason, at HHS/CDC's sole discretion.

Participation in this Contest constitutes a contestants' full and unconditional agreement to abide by the Contest's Official Rules found at *www.Challenge.gov.*

Authority: 15 U.S.C. 3719.

Dated: August 14, 2012.

Tanja Popovic,

Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2012–20485 Filed 8–20–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0891]

Post-Approval Studies 2012 Workshop: Design, Methodology, and Role in Evidence Appraisal Throughout the Total Product Life Cycle; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Post-Approval Studies 2012 Workshop: Design, Methodology, and Role in Evidence Appraisal Throughout the Total Product Life Cycle.'' The topics of discussion will include lessons learned from previous experiences with post-approval studies, improvement of implementation strategies for post-approval studies, best practices, and innovative methodologies for evidence appraisal.

Date and Time: The public workshop will be held on August 30, 2012, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Persons: Nilsa Loyo-Berrios, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3214, Silver Spring, MD 20993, 301–796–8528, email: *Nilsa.Loyo-Berrios @fda.hhs.gov* or Danica Marinac-Dabic, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4110, Silver Spring, MD 20993, 301–796–6689, email: *Danica.Marinac-Dabic@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 5 p.m. on August 23, 2012. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. Onsite registration will not be available on the day of the public workshop.

If you need special accommodations due to a disability, please contact Cindy Garris, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg., 66, Rm. 4321, Silver Spring, MD 20993, 301–796–5861, email: *Cynthia.garris@fda.hhs.gov.*

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email,

and telephone number. Those without Internet access should contact Nilsa Loyo-Berrios to register (see *Contact Persons*). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by 5 p.m. on August 28, 2012. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Web cast participants will be sent technical system requirements after registration and will be sent connection access information after August 23, 2012. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Comments: FDA is holding this public workshop to provide an update and obtain stakeholders input on post-approval studies ordered at the time of device approval. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is September 30, 2012.

Regardless of attendance at the public workshop, interested persons may submit either written comments regarding this document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 or electronic comments to *http://www.regulations.gov.* It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

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 hardcopy 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. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (Select this public workshop from the posted events list).

SUPPLEMENTARY INFORMATION:

I. Background

Post-approval studies (PAS) are imposed as conditions of approval for some class III devices regulated under premarket approval (PMA) regulations and are an important public health tool for developing additional evidence on device performance in the postmarket setting. In order for PAS to be most effective, studies must be well-designed, scientifically sound, meaningful and feasible, and must provide complete and timely information. PMA conditions of approval studies are constructed to ask for specific, detailed data in a subsequent PAS relating to unanswered questions in premarket data. However, there are often opportunities for leveraging the design and conduct of PAS, enhancing its utility to other important stakeholders. In addition to the direct role of PMA holders, the role of other public health partners is expanding, as evidenced by a number of efforts external to CDRH that are directly or indirectly involved in collecting and analyzing data relevant to estimating medical device use and risk and in communicating risk to target populations. To ensure a successful PAS program, CDRH, regulated industry, clinical researchers, and other stakeholders must remain well-informed and engaged in continuous dialogue regarding the design, implementation, reporting, and use of PAS and the resultant data. Further, it is the Center's desire to ensure this dialogue results in studies that maximize the public health impact by producing data that is informative to a range of stakeholders.

II. Topics for Discussion at the Public Workshop

We intend to discuss a large number of issues at the workshop, including, but not limited to the following: (1) PAS within the Total Product Life Cycle, (2) best practices and improvement of PAS implementation strategies, (3) PAS impact on public health and medical device innovation, and (4) opportunities for innovative uses of PAS data.

Dated: August 15, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–20469 Filed 8–20–12; 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; Translational Research.

Date: September 19, 2012.

Time: 11:00 a.m. to 5:00 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: Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 753, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8898, *barnardm@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Diabetes Ancillary Studies.

Date: October 10, 2012.

Time: 2:00 p.m. to 4:00 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: D.G. Patel, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 756, 6707 Democracy Boulevard,