II. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: November 16, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–25248 Filed 11–21–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6230]

Tenth Annual Sentinel Initiative; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Tenth Annual Sentinel Initiative Public Workshop.'' The purpose of this 2-day public workshop is to bring the stakeholder community together to discuss a variety of topics on active medical product surveillance. Attendees will leave with a deeper understanding of how to use the Sentinel System tools to address safety questions.

DATES: The public workshop will be held on February 7 and 8, 2018. Day 1 of the public workshop will be held on February 7, 2018, from 9 a.m. to 4:30 p.m. Day 2 of the public workshop will be held on February 8, 2018, from 9 a.m. to 2 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at two separate locations. On Day 1 the public workshop will be held at the Hyatt Regency Bethesda, 1 Bethesda Metro Center, Bethesda, MD 20814. On Day 2 the public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503 (the Great Room), Silver Spring, MD 20993–0002. 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 *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander Jamila Mwidau, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 22, Rm. 4481, Silver Spring, MD 20993; 301–796–4989, *Jamila.Mwidau@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this 2-day public workshop is to bring the stakeholder community together to discuss a variety of topics on active medical product surveillance. Day 1 will be convened by the Duke-Margolis Center for Health Policy at Duke University with support by a cooperative agreement with FDA. Key discussion topics will include an update on the state of FDA's Sentinel Initiative, key safety surveillance activities, and emerging uses of the Sentinel System. In addition, panelists, representing diverse stakeholder perspectives, will provide comments on Sentinel and opportunities to expand its analytic capabilities. This workshop will also provide an opportunity for stakeholder engagement and input on Sentinel's continued modernization.

Day 2 will be a public workshop sponsored by FDA targeting researchers who are experienced in using claims data and will build upon prior public training conducted by FDA on July 10, 2017 (82 FR 19063, April 25, 2017). This second day of the workshop will address more advanced training topics, including Sentinel's inferential analytic capabilities and methods of identifying unexpected safety concerns. Attendees will leave with a deeper understanding of how to use the Sentinel System tools to address safety questions. Attendees are encouraged to review the material FDA presented on July 10, 2017, by visiting the Web site: *https://www.sentinelinitiative.org/communications/sentinel-initiative-events/public-sentinel-training-fda.*

II. Participating in the Public Workshop

Registration: To attend the public workshop, you may register for one or both days, but you must register for each day of the workshop separately. The Duke-Margolis Center for Health Policy at Duke University will manage registration for Day 1 and FDA will manage registration for Day 2.

Day 1: To attend the public workshop on Day 1, you must register before February 6, 2018, by visiting *https://healthpolicy.duke.edu/events/10th-annual-sentinel-public-workshop.* You may also register for the live webcast by visiting this Web page. There will be no onsite registration.

When registering, please provide the following information: Your name, title, company or organization (if applicable), postal address, telephone number, and email address. There is no registration fee. However, registration will be on a first-come, first-served basis because seating is limited. A 1-hour lunch break is scheduled, but food will not be provided. There are multiple restaurants within walking distance of Hyatt Regency Bethesda. If you need special accommodations due to a disability, please contact Elizabeth Murphy at the Duke-Margolis Center for Health Policy (202–621–2801, email: *elizabeth.g.murphy@duke.edu*) no later than February 6, 2018.

Streaming Webcast for Day 1: The workshop will be webcast (archived video footage will be available following the workshop at *https://healthpolicy.duke.edu/events/10th-annual-sentinel-public-workshop*). Persons interested in viewing the live webcast must register online before February 6, 2018. Early registration is recommended because webcast connections are limited. Webcast participants will be sent technical system requirements in advance of the event. Prior to joining the streaming webcast of the public workshop, it is recommended that you review these technical system requirements.

All Day 1 event materials will be available to registered attendees via email before the workshop at the Duke-Margolis Web site at *https://healthpolicy.duke.edu/events/10th-annual-sentinel-public-workshop.*

Day 2: To register to attend Day 2 of the workshop in person or virtually via webcast, you must register before February 6, 2018, by visiting: *https://www.eventbrite.com/e/february-8-2018-training-at-fda-tickets-37914164286.*

Please provide complete contact information for each attendee, including name, title, affiliation, telephone number, and email address. Registration is free and based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration will be provided beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Lieutenant Commander Jamila Mwidau no later than January 24, 2018.

Streaming Webcast of the Public Workshop Day 2: The FDA training

public workshop will also be webcast at *https://collaboration.fda.gov/sentinelworkshop.*

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 *https://www.adobe.com/go/connectpro_overview.* FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Transcripts: Please be advised that transcripts of the 2-day public workshop will not be available.

Dated: November 16, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–25251 Filed 11–21–17; 8:45 am]

BILLING CODE 4164–01–P

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, 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; Small Business: Musculoskeletal Rehabilitation Sciences.

Date: December 1, 2017.

Time: 12:00 p.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Baljit S. Moonga, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7806, Bethesda, MD 20892, 301–435–1777, *moongabs@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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Epidemiology, Ethical and Population Sciences II.

Date: December 11, 2017.

Time: 1:00 p.m. to 2:00 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: Gniesha Yvonne Dinwiddie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3137, Bethesda, MD 20892, *dinwiddiegy@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and Related Research.

Date: December 13–14, 2017.

Time: 10:00 a.m. to 9:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Kenneth A. Roebuck, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5106, MSC 7852, Bethesda, MD 20892, (301) 435–1166, *roebuckk@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: November 16, 2017.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–25215 Filed 11–21–17; 8:45 am]

BILLING CODE 4140–01–P

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, 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: Chemo/Dietary Prevention.

Date: December 4, 2017.

Time: 3:00 p.m. to 5:00 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: Sharon K. Gubanich, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6195D, MSC 7804, Bethesda, MD 20892, (301) 408–9512, *gubanics@csr.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: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Pulmonary Diseases.

Date: December 5–6, 2017.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Bradley Nuss, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4142, MSC7814, Bethesda, MD 20892, 301–451–8754, *nussb@csr.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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cardiovascular Sciences.

Date: December 6–7, 2017.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Kimm Hamann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118A, MSC 7814, Bethesda, MD 20892, 301–435–5575, *hamannkj@csr.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.

(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: November 16, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–25216 Filed 11–21–17; 8:45 am]

BILLING CODE 4140–01–P