

with a check or money order payable to "SoCRA". Mail to: SoCRA (see *Contact* for address). To register via the Internet, go to http://www.socra.org/html/FDA_Conference.htm. (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web site after this document is published in the **Federal Register**.)

Payment by major credit card is accepted (Visa/MasterCard/AMEX only). For more information on the meeting registration, or for questions on the workshop, contact SoCRA (see *Contact*).

SUPPLEMENTARY INFORMATION: The public conference helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements related to informed consent, clinical investigation requirements, IRB inspections, electronic record requirements, and investigator initiated research. Topics for discussion include the following: (1) What FDA Expects in a Pharmaceutical Clinical Trial; (2) Adverse Event Reporting—Science, Regulation, Error, and Safety; (3) Part 11 Compliance—Electronic Signatures; (4) Informed Consent Regulations; (5) IRB Regulations and FDA Inspections; (6) Keeping Informed and Working Together; (7) FDA Conduct of Clinical Investigator Inspections; (8) Meetings With FDA: Why, When, and How; (9) Investigator Initiated Research; (10) Medical Device Aspects of Clinical Research; (11) Working With FDA's Center for Biologics Evaluation and Research; (12) The Inspection Is Over—What Happens Next? Possible FDA Compliance Actions; (13) Ethical Issues in Subject Enrollment; (14) Medical Device Aspects of Clinical Research; and (15) Are We There Yet? An Overview of the FDA Good Clinical Practice Program.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The public workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The public workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) as outreach

activities by Government Agencies to small businesses.

Dated: August 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–19852 Filed 8–15–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Issues in the Design of Clinical Trials of Antibacterial Drugs for the Treatment of Non-Cystic Fibrosis Bronchiectasis; 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 focusing on the design of clinical trials of antibacterial drugs for the treatment of non-cystic fibrosis (non-CF) bronchiectasis. This public workshop is intended to provide information for, and gain perspective from, health care providers, patients and patient advocacy organizations, academia, and industry on various aspects of the design of clinical trials. The input from this public workshop will be useful in developing topics for further discussion.

Date and Time: The public workshop will be held on September 7, 2012, from 8 a.m. to 3:30 p.m.

Location: The public workshop will be held at the Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910. The hotel's phone number is 301–589–0800. Seating is limited and available on a first-come, first-served basis.

CONTACT PERSON FOR MORE INFORMATION: Christine Moser or Lori Benner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6204, Silver Spring, MD 20993–0002, 301–796–1300.

Registration: Registration is free for the public workshop. Interested parties are encouraged to register early. Seating will be available on a first-come, first-served basis. To register electronically, email your registration information (including name, title, firm name, address, telephone, and fax number) to bronchiectasisworkshop@fda.hhs.gov. Those without access to the Internet may call 301–796–1300 to register. Persons needing a sign language

interpreter or other special accommodations should notify Christine Moser or Lori Benner (see **CONTACT PERSON FOR MORE INFORMATION**) at least 7 days in advance.

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 (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD–ROM after submission of a Freedom of Information request. Written requests should be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Transcripts will also be available on the Internet (<http://www.fda.gov/Drugs/NewsEvents/ucm305463.htm>) approximately 45 days after the workshop.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop focusing on scientific considerations in the design of clinical trials of antibacterial agents for the treatment of non-CF bronchiectasis. Discussions will focus on natural history; patient populations for enrollment in clinical trials; current standard of care and unmet need; clinical trial endpoints, including exacerbation and patient-reported outcomes; and clinical trial design elements, including duration of treatment and patient followup.

FDA encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

Dated: August 10, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–20106 Filed 8–15–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 Cancer Institute Special Emphasis Panel; Small Grants for Behavioral Research in Cancer Control.

Date: September 18–19, 2012..

Time: 9 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6130 Executive Blvd., Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Gerald G. Lovinger, Ph.D., Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Room 8101, Bethesda, MD 20892–8329, 301–496–7987, lovingeg@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI REVIEW of P50 and R01 applications in Lung, Skin, Ovarian, Pancreatic and Gastrointestinal Cancers.

Date: September 19–20, 2012.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Caron A Lyman, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Room 8119, Bethesda, MD 20892–8328, 301–451–4761, lymanc@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI SPORE II.

Date: September 19–20, 2012.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Wlodek Lopaczynski, MD, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd. Room 8131, Bethesda, MD 20892, 301–594–1402, lopacw@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Emerging Technologies in Biospecimen Science.

Date: October 24, 2012.

Time: 12 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6116 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Donald L Coppock, Ph.D., Scientific Review Officer, Scientific Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH 6116 Executive Blvd., Room 7151 Bethesda,

MD 20892 301–451–9385

donald.coppock@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Core Infrastructure and Methodological Research for Cancer Epidemiology Cohorts.

Date: October 31, 2012.

Time: 11 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health 6120 Executive Blvd. Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Kenneth L. Bielat, Ph.D., Scientific Review Officer, Special Review Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 7147, Bethesda, MD 20892–8329, 301–496–7576, bielatk@mail.nih.gov.

Information is also available on the Institute's/Center's home page: <http://deainfo.nci.nih.gov/advisory/sep/sep.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: August 13, 2012.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–20159 Filed 8–15–12; 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 (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: Biodata Analysis and Biosystems Modeling.

Date: September 12, 2012.

Time: 2 p.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: Kee Hyang Pyon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, MSC 7806, Bethesda, MD 20892, pyonkh2@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Neurobiology of Integrative Brain Functions.

Date: September 17, 2012.

Time: 2:30 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Wei-Qin Zhao, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5181 MSC 7846, Bethesda, MD 20892–7846, 301–435–1236, zhaow@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: August 13, 2012.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–20158 Filed 8–15–12; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–NEW]

Agency Information Collection Activities: Consideration of Deferred Action for Childhood Arrivals, Form I–821D, New Information Collection; Emergency Submission to the Office of Management and Budget; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review.

The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS), submitted the following emergency information collection request, utilizing emergency review procedures, to the Office of Management and Budget (OMB) for review and clearance in