

TABLE 1—Continued

Committee name	Tentative date(s) of meeting(s)
Medical Devices Dispute Resolution Panel .....	Date(s), if needed, to be determined.
Microbiology Devices Panel .....	Date(s), if needed, to be determined.
Molecular and Clinical Genetics Panel .....	June 27.
Neurological Devices Panel .....	Date(s), if needed, to be determined.
Obstetrics and Gynecology Devices Panel .....	July 5–6.
Ophthalmic Devices Panel .....	November 8–9.
Orthopedic and Rehabilitation Devices Panel .....	September 13–14, November 16, December 6–7.
Radiological Devices Panel .....	November 2.
National Mammography Quality Assurance Advisory Committee .....	October 18.
Technical Electronic Product Radiation Safety Standards Committee ....	June 14.
<b>CENTER FOR FOOD SAFETY AND APPLIED NUTRITION</b>	
Food Advisory Committee .....	December 13–14.
<b>CENTER FOR TOBACCO PRODUCTS</b>	
Tobacco Products Scientific Advisory Committee .....	January 18–20, March 1–2.
<b>CENTER FOR VETERINARY MEDICINE</b>	
Veterinary Medicine Advisory Committee .....	Date(s), if needed, to be determined.
<b>NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH (NCTR)</b>	
Science Advisory Board to NCTR .....	October 23–24.

Dated: December 14, 2011.

**Jill Hartzler Warner,**  
*Acting Associate Commissioner for Special Medical Programs.*  
 [FR Doc. 2011–32469 Filed 12–19–11; 8:45 am]  
**BILLING CODE 4160–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2011–N–0002]

**Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice; Public Workshop**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA), Los Angeles District Office, in cosponsorship with the Society of Clinical Research Associates (SoCRA), is announcing a public workshop. The public workshop on FDA’s clinical trial requirements is designed to aid the clinical research professional’s understanding of the mission, responsibilities, and authority of the FDA and to facilitate interaction with FDA representatives. The program will focus on the relationships among FDA and clinical trial staff, investigators, and institutional review boards (IRB). Individual FDA representatives will discuss the informed consent process

and informed consent documents; regulations relating to drugs, devices, and biologics; as well as inspections of clinical investigators, of IRB, and research sponsors.

*Date and Time:* The public workshop will be held on March 7 and 8, 2012, from 8 a.m. to 5 p.m.

*Location:* The public workshop will be held at the Hyatt Regency Newport Beach, 1107 Jamboree Rd., Newport Beach, CA 92660, 1 (949) 729–1234.

Attendees are responsible for their own accommodations. Please mention SoCRA to receive the hotel room rate of \$145.00 plus applicable taxes (available until February 14, 2012, or until the SoCRA room block is filled).

*Contact:* Linda Hartley, Office of Regulatory Affairs, Food and Drug Administration, 19701 Fairchild, Irvine, CA 92612, (949) 608–4413, FAX: (949) 608–4417; or Society of Clinical Research Associates (SoCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914, 1 (800) 762–7292 or (215) 822–8644; FAX: (215) 822–8633, email [SoCRAMail@aol.com](mailto:SoCRAMail@aol.com), Web site: [www.socra.org](http://www.socra.org).

*Registration:* The registration fee will cover actual expenses including refreshments, lunch, materials, and speaker expenses. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order of receipt of registration. Those accepted into the public workshop will receive confirmation. The cost of the registration is as follows:

**COST OF REGISTRATION**

SoCRA nonmember (includes membership) .....	650.00
Federal Government SoCRA member .....	450.00
Federal Government SoCRA non-member .....	525.00
FDA Employee .....	[*]

\* Fee Waived.

If you need special accommodations due to a disability, please contact SoCRA or Linda Hartley (see *Contact*) at least 21 days in advance.

Extended periods of question and answer and discussion have been included in the program schedule. SoCRA designates this education activity for a maximum of 13.3 Continuing Education (CE) Credits for SoCRA CE and continuing nurse education (CNE). SoCRA designates this educational activity for a maximum of 13.3 American Medical Association Physician’s Recognition Award *Category 1 Credit(s)*<sup>TM</sup>. Physicians should claim only the credit commensurate with the extent of their participation. SoCRA is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. SoCRA is an approved provider of CNE by the Pennsylvania State Nurses Association (PSNA), an accredited approver by the American Nurses Credentialing Center’s Commission on Accreditation (ANCC).

ANCC/PSNA Provider Reference Number: 205-3-A-09.

**Registration Instructions:** To register, please submit a registration form with your name, affiliation, mailing address, telephone, fax number, and email, along 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](http://www.socra.org/html/FDA_Conference.htm). (FDA has verified the Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document publishes 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 public workshop, contact SoCRA (see *Contact*).

**SUPPLEMENTARY INFORMATION:** The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The public 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; and (12) The Inspection Is Over—What Happens Next? Possible FDA Compliance Actions.

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 (Public Law 104-121) as outreach activities by Government Agencies to small businesses.

Dated: December 14, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-32435 Filed 12-19-11; 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 RFA Panel: Challenge on the Transition from Acute to Chronic Neuropathic Pain

*Date:* January 9-10, 2012.

*Time:* 8 a.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:* 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](mailto:bishopj@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel Member Conflict: Topics in Infectious Diseases and Microbiology

*Date:* January 12, 2012.

*Time:* 1 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:* Liangbiao Zheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, MSC 7808, Bethesda, MD 20892, (301) 996-5819, [zhengli@csr.nih.gov](mailto:zhengli@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: December 13, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011-32520 Filed 12-19-11; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Office of the Secretary

#### Published Privacy Impact Assessments on the Web

**AGENCY:** Privacy Office, DHS.

**ACTION:** Notice of Publication of Privacy Impact Assessments (PIA).

**SUMMARY:** The Privacy Office of DHS is making available seven PIAs on various programs and systems in DHS. These assessments were approved and published on the Privacy Office's web site between September 1, 2011 and November 30, 2011.

**DATES:** The PIAs will be available on the DHS Web site until February 21, 2012, after which they may be obtained by contacting the DHS Privacy Office (contact information below).

**FOR FURTHER INFORMATION CONTACT:** Mary Ellen Callahan, Chief Privacy Officer, Department of Homeland Security, Washington, DC 20528, or email: [pia@hq.dhs.gov](mailto:pia@hq.dhs.gov).

**SUPPLEMENTARY INFORMATION:** Between September 1, 2011 and November 30, 2011, the Chief Privacy Officer of the DHS approved and published seven Privacy Impact Assessments (PIAs) on the DHS Privacy Office web site, [www.dhs.gov/privacy](http://www.dhs.gov/privacy), under the link for "Privacy Impact Assessments." These PIAs cover seven separate DHS programs. Below is a short summary of those programs, indicating the DHS component responsible for the system, and the date on which the PIA was approved. Additional information can be found on the web site or by contacting the Privacy Office.

*System:* DHS/FEMA/PIA-018 Suspicious Activity Reporting (SAR).

*Component:* Federal Emergency Management Agency (FEMA).

*Date of approval:* September 9, 2011.

FEMA, a component of DHS, manages a process for SAR. This process, assigned to FEMA's Office of the Chief Security Officer, is designed to collect, investigate, analyze, and report suspicious activities to the Federal Bureau of Investigation's (FBI) Joint