Location: The public workshop will be held at the Marriott Ann Arbor Ypsilanti at Eagle Crest, 1275 S. Huron St., Ypsilanti, MI 48197, 800–606–7044.

Contact: 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,* Web site: *http://www.SoCRA.org.* (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**.); or Nancy Bellamy, Food and Drug Administration, Detroit District Office, 300 River Pl., Suite 5900, Detroit, MI 48207, 313–393–8143, Fax: 313–393–8139, email: *nancy.bellamy@fda.hhs.gov.*

Accommodations: Attendees are responsible for their own accommodations. Please mention SoCRA to receive the hotel room rate of $119 plus applicable taxes (available until April 17, 2012 or until the SoCRA room block is filled).

COST OF REGISTRATION

SoCRA member	$575
SoCRA nonmember (includes membership)	650
Federal Government member	450
Federal Government non-member	525
FDA Employee	*

* (Free) Fee Waived.

If you need special accommodations due to a disability, please contact SoCRA (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 educational activity for a maximum of 13.3 Continuing Education Credits for SoCRA CE and Nurse CNE. SoCRA designates this live activity for a maximum of 13.3 AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation. CME for Physicians: SoCRA is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. CNE for Nurses: SoCRA is an approved provider of continuing nursing education 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.* 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 workshop 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; (15) Are We There Yet? An Overview of the FDA GCP 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: February 9, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–3553 Filed 2–14–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director Notice of Establishment

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. App), the Director, National Institutes of Health (NIH), announces the establishment of the National Center for Advancing Translational Sciences Advisory Council (Council) and the Cures Acceleration Network Review Board (Board), in the National Center for Advancing Translation Sciences (NCATS).

The Council will advise, assist, consult with, and make recommendations to the Secretary of Health and Human Services (Secretary), the Director, National Institutes of Health (NIH) and the Director, National Center for Advancing Translational Sciences (NCATS, also referred to as Center) on matters related to the activities carried out by and through the Center and the policies respecting these activities.

The Board will advise, and provide recommendation to, the Director, NCATS, with respect to (1) policies, programs, and procedures for carrying out the duties of the Director, NCATS, under section 480 of the PHS Act; and (2) significant barriers to successful translation of basic science into clinical application (including issues under the purview of other agencies and departments).

Duration of each committee is two years from the date the Charter is filed.

Dated: February 7, 2012.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2012–3572 Filed 2–14–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as