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: 205–3–1–09.

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://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 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 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) Are We There Yet?; (2) What FDA Expects in a Pharmaceutical Clinical Trial; (3) Medical Device Aspects of Clinical Research; (4) Adverse Event Reporting—Science, Regulation, Error, and Safety; (5) Working With FDA's Center for Biologics Evaluation and Research; (6) Ethical Issues in Subject Enrollment; (7) Keeping Informed and Working Together; (8) FDA Conduct of Clinical Investigator Inspections; (9) Investigator Initiated Research; (10) Meetings with FDA—Why, When, and How; (11) Part 11 Compliance—Electronic Signatures; (12) IRB Regulations and FDA Inspections; (13) Informed Consent Regulations; and (14) 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 (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. 2012–19851 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]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Dallas District Office, in co-sponsorship 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 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 (IRBs). 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, IRBs, and research sponsors.

Date and Time: The public workshop will be held on March 6 and 7, 2013, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Sheraton Dallas Hotel, 400 North Olive St., Dallas, TX 75201, 214–922–8000.

Attendees are responsible for their own accommodations. Please mention SoCRA to receive the hotel room rate of $145 plus applicable taxes (available until February 3, 2013, or until the SoCRA room block is filled).

Contact: David Arvelo, Office of Regulatory Affairs, Food and Drug Administration, Southwest Regional Office, 4040 North Central Expressway, Suite 900, Dallas, TX 75204, 214–253–4952, Fax: 214–253–4970, email: *david.arvelo@fda.hhs.gov* or SoCRA, 530 West Butler Ave., Suite 109, Chalfont, PA 18914, 800–762–7292, FAX: 215–822–8633, email: *SoCRAmail@aol.com,* Web site: *http://www.SoCRA.org*.

Registration: The registration fee covers the cost of 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 workshop will receive confirmation. The cost of registration is as follows:

SoCRA member, $575.00
SoCRA nonmember (includes membership), $650.00
Federal Government SoCRA member, $450.00
Federal Government SoCRA nonmember, $525.00
FDA Employee, 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 (CE) credits for SoCRA CE and Nurse continuing nursing education (CNE). SoCRA designates this educational activity for a maximum of 13.3 American Medical Association Physicians Recognition Award Category 1 Credit(s)™. Physicians should claim 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, phone, 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.* (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]

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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 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