SUMMARY: The Food and Drug Administration (FDA) New Jersey 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 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 November 4 and 5, 2010, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Hyatt Regency Jersey City, Two Exchange Pl., Jersey City, NJ 07302, 1–800–233–1234. (The hotel is connected to the PATH Train to New York City). Attendees are responsible for their own accommodations. Please mention SoCRA to receive the hotel room rate of $169 plus applicable taxes (available until October 20, 2010, or until the SoCRA room block is filled).

Contact: Joan Lytle, Food and Drug Administration, 120 North Central Dr., North Brunswick, NJ 08902, 732–940–8946 ext. 33, FAX: 732–940–8936, or Society of Clinical Research Associates (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 or 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), FDA/Federal Government member ($450.00), FDA/Federal Government nonmember ($525.00).

If you need special accommodations due to a disability, please contact SoCRA (see *Contact*) at least 10 days in advance.

Extended periods of question and answer and discussion have been included in the program schedule. This program offers 13.3 hours of continuing medical education (CME) and continuing nursing education (CNE) credit. *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, 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 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 workshop, contact SoCRA (see *Contacts*).

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.

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: August 17, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–20834 Filed 8–20–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Quality and Compliance in Merging and Emerging Cultures; Public Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public conference entitled "The New Paradigm: Quality and Compliance in Merging and Emerging Cultures." The conference, cosponsored with the Parenteral Drug Association (PDA), will focus on challenges facing the medical products industry in navigating regulatory compliance, achieving worldwide quality improvement, and enhancing quality system controls in an environment of merging and emerging cultures.

Date and Time: The public conference will be held on Monday, September 13, 2010, from 7 a.m. to 6 p.m.; Tuesday, September 14, 2010, from 7:30 a.m. to 6:30 p.m.; and Wednesday, September 15, 2010, from 7:30 a.m. to 12:15 p.m.

Location: The public conference will be held at the Renaissance Hotel, 999 9th St., NW., Washington, DC 20001, 202–898–9000, FAX: 202–289–0947.

Contact: Wanda Neal, Parenteral Drug Association, PDA Global Headquarters, Bethesda Towers, 4350 East-West Hwy., suite 200, Bethesda, MD 20814, 301–656–5900, FAX: 301–986–1093, email: *info@pda.org*.

Accommodations: Attendees are responsible for their own

accommodations. To make reservations at the Renaissance Hotel at the reduced conference rate, contact the Renaissance Hotel (see *Location*), citing meeting code "PDA." Room rates are: Single: $288, plus 14.5% state and local taxes and Double: $288, plus 14.5 state and local taxes. Reservations can be made on a space and rate availability basis.

Registration: Attendees are encouraged to register at their earliest convenience. The PDA registration fees cover the cost of facilities, materials, and refreshments. Seats are limited; please submit your registration as soon as possible. Conference space will be filled in order of receipt of registration. Those accepted for the conference will receive confirmation. Registration will close after the conference is filled. Onsite registration will be available on a space available basis on each day of the public conference beginning at 7 a.m. on Monday, September 13, 2010. The cost of registration is as follows:

COST OF REGISTRATION

Affiliation	Fee
PDA Members	$1850
PDA Non-Members	$2099
Government	$700
PDA Member Academic/ Health Authority	$700
PDA Non-Member Academic/Health Authority	$800
PDA Member Students	$280
Non-Member Students	$310

If you need special accommodations because of a disability, please contact Wanda Neal, at least 7 days in advance of the conference.

Registration instructions: To register, please submit your name, affiliation, mailing address, telephone, fax number, and email address, along with a check or money order payable to "PDA." Mail to: PDA, Global Headquarters, Bethesda Towers, 4350 East West Hwy., suite 200, Bethesda, MD 20814. To register via the Internet, go to the PDA Web site, *https://store.pda.org/events/registration/registration_start_choose_type*. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

The registrar will also accept payment by major credit cards (VISA/MasterCard only). For more information on the meeting, or for questions on registration, contact the PDA (see *Contact*).

Transcripts: As soon as a transcript is available, it can be obtained in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: The PDA/FDA Joint Public Conference offers the unique opportunity for participants to join FDA representatives and industry experts in face-to-face dialogues. Each year, FDA speakers provide updates on current efforts affecting the development of global regulatory strategies, while industry professionals from some of today's leading pharmaceutical companies present case studies on how they employ global strategies in their daily processes.

Through a series of sessions and meetings, the conference will provide participants with the opportunity to hear directly from FDA experts and representatives of global regulatory authorities on best practices, including:

- Pharmaceutical Safety and Good Distribution Practices
- Patient Requirements and Product Development
- Quality Unit Responsibility
- Continual Improvement
- Technology Transfer
- Supply Chain
- Combination Products
- Recall Root Causes
- Biologics
- Knowledge Management
- Foreign Inspection Practices
- Process Validation
- Risk Management in Manufacturing
- Change Control

Dated: August 18, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–20844 Filed 8–20–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 Institute on Aging Special Emphasis Panel; Genetics of Aging in Drosophila.

Date: September 15, 2010.

Time: 12 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Bita Nakhai, PhD, Scientific Review Officer, Scientific Review Branch, National Institute on Aging, Gateway Bldg., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814, 301–402–7701, *nakhaib@nia.nih.gov*.

Name of Committee: National Institute on Aging Special Emphasis Panel; Aging Bone.

Date: September 29, 2010.

Time: 11 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Alicja L. Markowska, PhD, DSC, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–496–9666, *markowsa@nia.nih.gov*.

Name of Committee: National Institute on Aging Special Emphasis Panel; Health and Well-Being.

Date: December 1, 2010.

Time: 3 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jeannette L. Johnson, PhD, Scientific Review Officer, National Institutes on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7705, *johnsonj9@nia.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 17, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–20868 Filed 8–20–10; 8:45 am]

BILLING CODE 4140–01–P