ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) Center for Drug Evaluation and Research, in cosponsorship with the International Society for Pharmaceutical Engineering (ISPE), is planning a multiday, educational public workshop entitled ''Redefining the 'C' in CGMP: Creating, Implementing, and Sustaining a Culture of Compliance.''

DATES: *Date and Time:* The public workshop will be held on June 4, 2012, 9 a.m. to 5 p.m. and June 5, 2012, 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Renaissance Baltimore Harborplace Hotel, 202 E. Pratt St., Baltimore, MD 21202, 1–800–535–1201.

Contact Persons: FDA Contact: Rhonda Hill, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4341, Silver Spring, MD 20993, 301–796–3267, *rhonda.hill@fda.hhs.gov.*

ISPE Contact: Julianne Rill, Continuing Education Program Manager, 600 N. Westshore Blvd., Suite 900, Tampa, FL 33609; Web site: *http://www.ispe.org/2012-gmp-conference;* email: *jrill@ispe.org.* (FDA has verified the Web site address in this announcement but we are not responsible for any subsequent changes to the Web site in this announcement after this document publishes in the **Federal Register.**)

Accommodations: Attendees are responsible for their own accommodations. Please mention ISPE/FDA Conference to receive the hotel room rate of $195.00 plus applicable taxes (available until May 7, 2012, or until the ISPE room block is filled).

If you need special accommodations due to a disability, please contact ISPE (see *Contact Persons*) at least 7 days in advance of the meeting.

Registration: The ISPE registration fees cover the cost of facilities, materials, and refreshments. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order of receipt of registration. Those accepted for the workshop will receive confirmation. Registration will close after the workshop is filled.

COST OF REGISTRATION

ISPE member	$1,695
ISPE nonmember (includes membership).	2,035
Federal Government	750
FDA Planning Committee members and invited speakers.	Fee waived.

Please visit ISPE's Web site to confirm the prevailing registration fees.

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 ''ISPE.'' To register via the Internet, go to *http://www.ispe.org/2012-gmp-conference.* The registrar will accept payment by major credit card (Visa/MasterCard/AMEX only). For more information on the meeting registration, or for questions on the workshop, contact ISPE (see *Contact Persons*).

SUPPLEMENTARY INFORMATION: The 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 drug manufacturing operations with information on a number of topics concerning FDA requirements and expectations related to current good manufacturing practice (CGMP). The joint public workshop offers the 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 strategies to manufacture high quality drugs 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. Topics for discussion include the following: (1) The Business Case For Change; (2) Quality Risk Management—When, What, and How; (3) Sustaining Compliance Consistency Throughout Your Company and Supplier Network; (4) IT Strategies—Cloud Computing, RFID, and Beyond; (5) The Future of Drug Manufacturing. To help ensure the quality of FDA regulated products, the workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (Pub. L. 105–115), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The 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: May 1, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–10894 Filed 5–4–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Educational Forum on Medical Device Reporting, Complaint Files, and Recalls, Corrections, and Removals; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Southwest Region (SWR), Dallas District Office (DALDO), in collaboration with the FDA Medical Device Industry Coalition (FMDIC), is announcing a public workshop entitled ''Educational Forum on Medical Device Reporting, Complaint Files, and Recalls, Corrections, and Removals.'' The purpose of the public workshop is to provide information about FDA's Medical Device Quality Systems Regulation (QSR) to the regulated industry, particularly small businesses.

DATES: *Date and Time:* The public workshop will be held on June 15, 2012, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Renaissance Dallas Hotel, 2222 Stemmons Freeway, Dallas, TX 75207. Directions and lodging information are available at the FMDIC Web site at *http://www.fmdic.org/.*

Contact Person: David Arvelo, Food and Drug Administration, 4040 North Central Expressway, Suite 900, Dallas, TX 75204, 214–253–4952, FAX: 214–253–4970, email *david.arvelo@fda.hhs.gov.*

Registration: FMDIC has a $250 early registration fee. Discounts for full-time students and government employees with valid identification are available. Early registration ends June 1, 2012. Registration is $300 thereafter. For more information on fees and/or to register online, please visit *http://www.fmdic.org/.* As an alternative, you may send registration information including name, title, firm name, address, telephone and fax numbers, and email, along with a check or money order for the appropriate amount payable to the FMDIC, to FMDIC Registrar, 4447 N. Central Expressway, Suite 110 PMB197, Dallas, TX 75205.

Registration on site will be accepted on a space available basis on the day of the public workshop beginning at 7:30 a.m. Please note that due to popularity, similar past events have reached maximum capacity well before the day of the event. The cost of registration at the site is $300 payable to the FMDIC. The registration fee will be used to offset expenses of hosting the event including continental breakfast, lunch, refreshments, venue, materials, audiovisual equipment, and other logistics associated with this event.

If you need special accommodations due to a disability, please contact David Arvelo (see *Contact Person*) at least 21 days in advance.

SUPPLEMENTARY INFORMATION: The workshop is being held in response to the interest in the topics discussed from small medical device manufacturers in the Dallas District area. This workshop helps achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is also consistent with the purposes of FDA's Regional Small Business Program, which are in part to respond to industry inquiries, develop educational materials, sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as an outreach activity by Government agencies to small businesses.

The goal of the workshop is to present information that will enable manufacturers and regulated industry to better comply with the Medical Device QSR. The following topics will be discussed at the workshop: (1) The role of complaint files, (2) medical device reporting, (3) medical device recalls, corrections, and removals, and (4) Corrective and Preventive Actions as They Relate to Complaints.

Transcripts: Transcripts of this event will not be available due to the format of this workshop. Handouts will be posted online at *http://www.fmdic.org/* or may be requested in writing from David Arvelo (see *Contact Person*), after the public workshop.

Dated: May 1, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–10893 Filed 5–4–12; 8:45 am]

BILLING CODE 4160–01–P

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; Presenilin and Alzheimer's Disease.

Date: June 4, 2012.

Time: 12:00 p.m. to 3:00 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: Alexander Parsadanian, Ph.D., Scientific Review Officer, National Institute on Aging, Gateway Building 2C/212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–496–9666, *parsadaniana@nia.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel; Signal Transduction and AD.

Date: June 20, 2012.

Time: 11:45 a.m. to 3:00 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: Alexander Parsadanian, Ph.D., Scientific Review Officer, National Institute on Aging, Gateway Building 2C/212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–496–9666, *parsadaniana@nia.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel Cognitive Decline in Aging Monkeys.

Date: June 29, 2012.

Time: 11:00 a.m. to 3:00 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: Alexander Parsadanian, Ph.D., Scientific Review Officer, National Institute on Aging, Gateway Building 2c/212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–496–9666, *parsadaniana@nia.nih.gov.*

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

Dated: May 1, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–10965 Filed 5–4–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

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 meeting.

The meeting 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 Alcohol Abuse and Alcoholism Special Emphasis Panel; Review of RFA AA–12–008.

Date: May 23–24, 2012.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIAAA, National Institutes of Health, 5635 Fishers Lane, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Ranga Srinivas, Ph.D., Chief, Extramural Project Review Branch EPRB, NIAAA, National Institutes of Health, 5365 Fishers Lane, Room 2085, Rockville, MD 20852, (301) 451–2067, *srinivar@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)