

*Name:* Council on Graduate Medical Education (COGME).

*Dates and Times:* April 22, 2010, 8:30 a.m.–4:15 p.m. EST; April 23, 2010, 8:30 a.m.–4:15 p.m. EST.

*Place:* DoubleTree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814, Telephone: (301) 652–2000.

*Status:* The meeting will be open to the public except on Friday, April 23 from 12 p.m.–1 p.m.

*Agenda:* On April 22, the meeting will be called to order with remarks from the COGME Chair and the Executive Secretary of COGME. There will be presentations addressing topics such as: (1) The adequacy of the pediatrician workforce physician supply; (2) the results of a recent study of primary care physician workforce projections by State; (3) the Bureau of Health Professions plans for healthcare workforce analytics; (4) a patient-centered primary care collaborative; and (5) the relationship between primary care, population health, and health care costs.

On April 23, there will be presentations on the workforce components of key health reform legislation and on challenges facing graduate medical education in the coming decade. The Council members will enter into a discussion and will formulate recommendations to the Secretary of Health and Human Services and the Congress as part of the Council's emerging report covering the primary care physician workforce.

*Agenda items are subject to change as priorities dictate.*

*For Further Information Contact:* Anyone interested in obtaining a roster of members or other relevant information should write or contact Jerald M. Katzoff, Executive Secretary, COGME, Division of Medicine and Dentistry, Bureau of Health Professions, Parklawn Building, Room 9A–27, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–4443. The Web address for information on the Council and the April 22–23, 2010 meeting agenda is <http://cogme.gov>.

COGME will join the National Advisory Council on Nursing Education and Practice (NACNEP), the Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD), and the Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL) on April 21, 2010 for the third Bureau of Health Professions (BHP) All Advisory Committee Meeting. Please refer to the **Federal Register** notice for the BHP All Advisory Committee Meeting for additional details.

*Supplementary Information:* Requests to make oral comments or to provide written comments to the Council should be sent to Jerald M. Katzoff, Executive Secretary, COGME, at the contact information above. Individuals who plan to attend and need special assistance should notify the office at the address and phone number above at least 10 days prior to the meeting. Members of the public will have the opportunity to provide comments at the meeting.

Dated: March 18, 2010.

**Sahira Rafiullah,**

*Director, Division of Policy and Information Coordination.*

[FR Doc. 2010–6586 Filed 3–24–10; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0001]**

### Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practices; Public Workshop

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

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA) Los Angeles District Office, in cosponsorship with the Society of Clinical Research Associates, Inc. (SoCRA) is announcing a public workshop entitled “FDA Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practices.” The public workshop is intended 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 the FDA and clinical trial staff, investigators, and investigational review boards (IRBs). Individual FDA representatives will discuss the informed consent process and informed consent documents, and 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 Wednesday and Thursday, May 5 and 6, 2010, 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, 949–729–1234.

*Contact:* Linda Hartley, Food and Drug Administration, 19701 Fairchild, Irvine, CA 92612, 949–608–4413, FAX: 949–608–4417. Attendees are responsible for their own accommodations. To make reservations at the Hyatt Regency Newport Beach, contact the Hyatt Regency Newport Beach (see *Location*).

*Registration:* The SoCRA registration fees cover 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. Registration will close after the workshop is filled. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the public workshop beginning at 8 a.m. The cost of registration is as follows: FDA employee (fee waived), Government employee member (\$450), Government employee nonmember (\$525), non-Government employee SoCRA member (\$575), non-Government employee non-SoCRA member (\$650).

If you need special accommodations due to a disability, please contact Linda Hartley (see *Contact*) at least 10 days in advance of the public workshop.

Extended periods of question and answer and discussion have been included in the program schedule.

*Registration instructions:* To register, please submit a registration form with your name, affiliation, mailing address, phone, fax number, and e-mail, along with a check or money order payable to “SoCRA.” Mail to: SoCRA, 530 West Butler Ave., suite 109, Chalfont, PA 18914. 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 address, but we are 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/AMEX only). For more information on the meeting, or for questions on registration, contact SoCRA at 800–762–7292 or 215–822–8644, FAX: 215–822–8633, or e-mail: [SoCRAmail@aol.com](mailto:SoCRAmail@aol.com).

**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, institutional review board 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? What are the 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 workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) as an outreach activity by Government agencies to small businesses.

Dated: March 19, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010–6579 Filed 3–24–10; 8:45 am]

**BILLING CODE 4160–01–S**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Disease Control and Prevention**

#### **Statement of Organization, Functions, and Delegations of Authority**

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 75 FR 10296, dated March 5, 2010) is amended to reflect the establishment of the Office of the Associate Director for Policy.

Section C–B, Organization and Functions, is hereby amended as follows: Delete in their entirety the title and functional statements for the CDC Washington Office (CAQ) and insert the following:

*Office of the Associate Director for Policy (CAQ).* The mission of CDC's Office of the Associate Director for Policy (OADP) is to bring about policies that result in demonstrable improvements in public health-globally and at the federal, state, and local levels.

In carrying out its mission, OADP: (1) Provides advice to CDC leadership in developing agency policy and legislative strategies; (2) creates and maintains partnerships to implement policy and legislative strategies; (3) implements key policies to improve public health; (4) ensures the agency's scientific credibility, reputation, and needs are respected and supported by policy makers and stakeholders.

*Office of the Director (CAQ1).* (1) Provides strategic advice to CDC leadership on overall agency direction and priorities, and drives CDC towards actions to reduce leading preventable causes of morbidity and mortality; (2) ensures organizational effectiveness in policy or strategy across the agency; (3) ensures capacity throughout CDC for policy and strategy; (4) leads the development and management of policy agendas with federal agencies and other organizations; (5) establishes strategy and maintains relations with key organizations and individuals working on public health policies or legislation.

*Office of Prevention through Healthcare (CAQ 12).* (1) Uses policy tools to gain the maximum preventive benefit from the clinical system and to integrate clinical care with community health interventions; (2) draws upon expertise and functional roles resident in other units of the Office of the Associate Director for Policy as well as from across CDC to apply that expertise and functionality to advancing prevention through healthcare; (3) crafts a coordinated agency response to implementing provisions of health reform legislation once it is enacted.

*Policy Research, Analysis, and Development Office (CAQB).* (1) Identifies and assists CDC leadership in establishing policy at multiple levels (federal, state, local, global and in the private sector); (2) conducts policy analysis (including regulatory, legal, economic); (3) develops and implements strategies (including regulatory, legal, economic) to deliver on policy priorities; (4) coordinates agency work with the healthcare system and other health-related organizations to advance CDCs policy agenda within the healthcare sector; (5) develops expertise in programs, regulations, and initiatives of other agencies that may provide opportunity for health impact; (6) builds relations with government agencies and other organizations to advance policy agendas, with a special emphasis on state and local agencies; (7) monitors and evaluates impact of policy implementation priorities; (8) identifies and assesses policy best practices and helps diffuse and replicate those practices; (9) leads the strengthening

and development of policy capacity and talent within CDC, as well as within the larger public health community; (10) leads the development and implementation of CDCs health policy research agenda; (11) ensures CDC operates in an integrated, consistent manner in policy-related activities; (12) leverages relationships with think tanks, policy consultancies, and academic institutions; (13) manages selected partner cooperative agreements and contracts that focus on policy; and (14) develops an agency-wide strategy related to advancing policy for partner relations that are managed elsewhere in CDC.

*CDC Washington Office (CAQC).* (1) Directs and manages CDC interactions with Congress; (2) leads the development and oversees the execution of appropriations strategies; (3) develops and executes legislative strategies; (4) builds Congressional relations; (5) tracks and analyzes legislation; (6) develops strategy and leads response efforts for Congressional oversight; (7) builds relations with government agencies and other organizations to advance policy agendas, with an emphasis on federal agencies; (8) protects and advances the agency's reputation, scientific credibility, and interests; (9) informs CDC leadership of current developments and provides insight into the Washington policy environment; (10) coordinates District of Columbia-area assignees and helps maximize their impact in supporting the agency's strategies and priorities.

Dated: March 11, 2010.

**William P. Nichols,**

*Acting Chief Operating Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2010–6375 Filed 3–24–10; 8:45 am]

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Disease Control and Prevention**

#### **Statement of Organization, Functions, and Delegations of Authority**

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