

prospective candidates should be sent to FDA by September 25, 2009.

**ADDRESSES:** All nominations for membership should be sent electronically to [cv@oc.fda.gov](mailto:cv@oc.fda.gov), or by mail to Advisory Committee Oversight & Management Staff, 5600 Fishers Lane (HF-4), rm. 14C03, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Erik P. Mettler, Office of Policy, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4324, Silver Spring, MD 20993, 301-796-4711, FAX: 301-847-3541, e-mail: [erik.mettler@fda.hhs.gov](mailto:erik.mettler@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The agency requests nominations for nonvoting industry representatives on the Tobacco Products Scientific Advisory Committee. Elsewhere in this issue of the **Federal Register**, FDA is publishing two separate documents announcing the establishment of the committee and the request for nomination of the Tobacco Products Scientific Advisory Committee.

### I. Center for Tobacco

Tobacco Products Scientific Advisory Committee

The Tobacco Products Scientific Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to the regulation of tobacco products. The Committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information, and recommendations to the Commissioner of Food and Drugs.

The Committee shall include three nonvoting members who are identified with industry interests. These members shall include one representative of the tobacco manufacturing industry, one representative of the interests of tobacco growers, and one representative of the interests of the small business tobacco manufacturing industry. This final position can be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Committee.

### II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION**

**CONTACT**) within 30 days of publication of this document. Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the Tobacco Products Scientific Advisory Committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner of Food and Drugs will select the nonvoting member to represent industry interests.

### III. Application Procedure

Individuals may self nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. A current curriculum vitae and the name of the committee of interest should be sent to the FDA contact person within the 30 days. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA has a special interest in ensuring that women, minority groups, individuals with physical disabilities, and small businesses are adequately represented on its advisory committees, and therefore, encourages, nominations for appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: August 19, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9-20483 Filed 8-25-09; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0664]

### Industry Exchange Workshop on Food and Drug Administration Drug and Device Requirements; Public Workshop

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

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA) Philadelphia District, in cosponsorship with the Society of Clinical Research Associates (SoCRA) is announcing a public workshop entitled: "FDA Clinical Trial Requirements, Regulations, Compliance and GCP." This 2-day public workshop is intended to provide information about FDA clinical trial requirements to the regulated industry.

*Date and Time:* The public workshop will be held on October 21, 2009, from 8:30 a.m. to 5 p.m. and October 22, 2009, from 8:30 a.m. to 5 p.m.

*Location:* The public workshop will be held at the Hyatt Regency Pittsburgh International Airport, 1111 Airport Blvd., Pittsburgh, PA 15231, 724-899-1234 or 1-800-233-1234.

Attendees are responsible for their own accommodations. To make reservations at the Hyatt Regency Hotel, contact the Hyatt Regency Hotel.

*Contact:* Marie Falcone, Food and Drug Administration, U.S. Customhouse, 200 Chestnut St., rm. 900, Philadelphia, PA 19106, 215-717-3703, FAX: 215-597-4660, e-mail: [marie.falcone@fda.hhs.gov](mailto:marie.falcone@fda.hhs.gov).

*Registration:* You are encouraged to register by October 19, 2009. The SoCRA registration fees cover the cost of facilities, materials, and breaks. Seats are limited; please submit your registration as soon as possible. Course space will be filled in order of receipt of registration. Those accepted in to the course will receive confirmation. Registration will close after the course 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:

#### COST OF REGISTRATION

Affiliation	Fee
FDA Employee	Fee Waived
Government (Non-Member)	\$525.00

## COST OF REGISTRATION—Continued

Affiliation	Fee
Non-Government (SoCRA Member)	\$575.00
Non-Government (Non SoCRA Member)	\$650.00

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

**Registration Instructions:** To register, please submit a registration form with your name, affiliation, mailing address, telephone, fax number, and e-mail address, 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 is not responsible for 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 public workshop, or for questions on registration, contact the Society of Clinical Research Associates 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 (IRB) inspections, electronic record requirements, and investigator initiated research. Topics for discussion include the following:

- What FDA Expects in a Pharmaceutical Clinical Trial;
- Adverse Event Reporting—Science, Regulation, Error, and Safety;
- Part 11 Compliance—Electronic Signatures;
  - Informed Consent Regulations;
  - IRB Regulations and FDA Inspections;
- Keeping Informed and Working Together;
  - FDA Conduct of Clinical Investigator Inspections;
  - Meetings With FDA: Why, When, and How;
  - Investigator Initiated Research;

- Medical Device Aspects of Clinical Research;

- Working With FDA’s Center for Biologics Evaluation and Research; and

- 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 18, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9-20340 Filed 8-25-09; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Board of Scientific Counselors, National Center for Public Health Informatics (BSC, NCPHI)

**Correction:** The notice was published in the **Federal Register** on August 18, 2009 [Volume 74, Number 158] [page 41712]. The “Matters To Be Discussed” has been revised: The board will discuss public health informatics issues related to the H1N1 virus; CDC public health informatics strategies and goals, including future program activities; and how the board can provide informatics scientific input to CDC.

**Contact Person for More Information:** Dr. Scott McNabb, National Center for Public Health Informatics, CDC, 1600 Clifton Road, NE., Mailstop E-78, Atlanta, Georgia 30333, Telephone (404) 498-6427, Fax (404) 498-6235.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the CDC and the Agency for Toxic Substance and Disease Registry.

Dated: August 18, 2009.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. E9-20575 Filed 8-25-09; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Complementary and Alternative Medicine Announcement of Wellness Workshop

**ACTION:** Notice.

**SUMMARY:** The National Center for Complementary and Alternative Medicine (NCCAM) invites the research community to participate in a workshop focused on wellness.

The purpose of this workshop is to review several measures of wellness, identify their strengths and weaknesses, and make recommendations on how best to capture the construct. This information will help NCCAM guide development of questions for the 2012 National Health Interview Survey.

The Workshop will take place on September 25, 2009. Those interested in CAM research are particularly encouraged to attend.

**Background:** The National Center for Complementary and Alternative Medicine (NCCAM) was established in 1999 with the mission of exploring complementary and alternative healing practices in the context of rigorous science, training CAM researchers, and disseminating authoritative information to the public and professionals. NCCAM funds research grants that explore the science of CAM. For more information, see <http://nccam.nih.gov/grants/whatnccamfunds/>.

**Participating:** The public is invited to attend and observe this workshop. Those interested in attending are required to RSVP via e-mail to Edward Culhane Jr. at [culhane@mail.nih.gov](mailto:culhane@mail.nih.gov) with their name, affiliation, e-mail and phone number. Space constraints limit the number of attendees at this workshop and participation will be on a first come, first served basis. For more information about what will be covered at the workshop, see <http://nccam.nih.gov/news/events/>.

**FOR FURTHER INFORMATION CONTACT:** To request more information, visit the NCCAM Web site at <http://nccam.nih.gov/news/events/>, call 301-594-3391 (Edward Culhane Jr.) or e-mail at [culhane@mail.nih.gov](mailto:culhane@mail.nih.gov).