ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Health Departments	Adult HIV Case Report	59	1,061	20/60
Health Departments	Pediatric HIV Case Report	59	5	20/60
Health Departments	Case Report Evaluations	59	107	20/60
Health Departments	Case Report Updates	59	1,576	2/60
Health Departments	Laboratory Updates	59	6,303	1/60
Health Departments	HIV Incidence Surveillance (HIS)	25	2,288	10/60
Health Departments	Molecular HIV Surveillance (MHS)	53	829	5/60
Health Departments	Perinatal HIV Exposure Reporting (PHER)	35	114	30/60
Health Departments	Annual Reporting: Standards Evaluation Report (SER).	59	1	8
Health Departments	Annual Reporting: Annual Performance Report (APR).	59	1	42

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–03046 Filed 2–12–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–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) is announcing the following public workshop entitled ''Educational Conference Co-Sponsored With the Society of Clinical Research Associates (SOCRA).'' 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, 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, of IRBs, and of research sponsors.

DATES: The public workshop will be held on March 9 and 10, 2016, from 8 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at the Holiday Inn San Diego Bayside, 4875 North Harbor Dr., San Diego, CA 92106, 619–224–3621.

FOR FURTHER INFORMATION CONTACT: Jane Kreis, Food and Drug Administration, 1301 Clay St., Suite 1180N, Oakland, CA 94612, 510–287–2708, FAX: 510–287–2739, or Society of Clinical Research Associates (SOCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914, telephone: 800–762–7292 or 215–822–8644, FAX: 215–822–8633, *Office@socra.org,* Web site: *www.socra.org.* (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 publishes in the **Federal Register**.)

SUPPLEMENTARY INFORMATION:

I. Background

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, IRB inspections, electronic record requirements, and investigator initiated research.

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 workshop helps to achieve objectives set forth in section 406 of the FDA 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. 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.

II. Topics for Discussion at the Public Workshop

Topics for discussion include the following: (1) The Role of the FDA District Office Relative to the Bioresearch Monitoring Program (BIMO); (2) Modernizing FDA's Clinical Trials/BIMO; (3) What FDA Expects in a Pharmaceutical Clinical Trial; (4) Medical Device Aspects of Clinical Research; (5) Adverse Event Reporting—Science, Regulation, Error, and Safety; (6) Working With FDA's Center for Biologics Evaluation and Research; (7) Ethical Issues in Subject Enrollment; (8) Keeping Informed and Working Together; (9) FDA Conduct of Clinical Investigator Inspections; (10) Investigator Initiated Research; (11) Meetings With FDA—Why, When, and How; (12) Part 11 Compliance—Electronic Signatures; (13) IRB Regulations and FDA Inspections; (14) Informed Consent Regulations; (15) The Inspection is Over—What Happens Next? Possible FDA Compliance Actions; and (16) Question and Answer Session/Panel Discussion.

Registration: The registration fee will cover 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 the registration is as follows: SOCRA member—$575, SOCRA nonmember (includes membership)—$650, Federal Government member—$450, Federal

Government nonmember—$525, and FDA Employee—(free) Fee Waived.

Attendees are responsible for their own accommodations. Please mention SOCRA to receive the hotel room rate of $142 plus applicable taxes (available until the SOCRA room block is filled).

If you need special accommodations due to a disability, please contact SOCRA (see **FOR FURTHER INFORMATION 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 education activity for a maximum of 13.3 Continuing Education (CE) Credits for SOCRA CE and Nurse CNE; SOCRA designates this live activity for a maximum of 13.3 AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation. *CME for Physicians:* SOCRA is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. *CNE for Nurses:* Society of Clinical Research Associates is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

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 **FOR FURTHER INFORMATION CONTACT**). To register via the Internet, go to *http://www.socra.org/html/FDAConference.htm.* 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 **FOR FURTHER INFORMATION CONTACT**).

Dated: February 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–02965 Filed 2–12–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Request for Nominations for Individuals and Consumer Organizations for Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any consumer organizations interested in participating in the selection of voting and/or nonvoting consumer representatives to serve on its advisory committees or panels notify FDA in writing. FDA is also requesting nominations for voting and/or nonvoting consumer representatives to serve on advisory committees and/or panels for which vacancies currently exist or are expected to occur in the near future. Nominees recommended to serve as a voting or nonvoting consumer representative may be self-nominated or may be nominated by a consumer organization.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests on an FDA advisory committee or panel may send a letter or email stating that interest to FDA (see **ADDRESSES**) by March 17, 2016, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by March 17, 2016. Nominations will be accepted for current vacancies and for those that will or may occur through March 31, 2016.

ADDRESSES: All statements of interest from consumer organizations interested in participating in the selection process and consumer representative nominations should be submitted electronically to *kimberly.hamilton@fda.hhs.gov,* by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002, or by FAX: 301–847–8640.

Consumer Representative nominations should be submitted electronically by logging into the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm,* by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002, or by FAX: 301–847–8640. Additional information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: *For questions relating to participation in the selection process:* Kimberly Hamilton, Advisory Committee Oversight and Management Staff (ACOMS), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32., Rm. 5117, Silver Spring, MD 20993–0002, 301–796–8224, email: *kimberly.hamilton@fda.hhs.gov.*

For questions relating to specific advisory committees or panels, contact the appropriate Contact Person listed in table 1 in the **SUPPLEMENTARY INFORMATION** section.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting that any consumer organizations interested in participating in the selection of voting and/or nonvoting consumer representatives to serve on its advisory committees or panels notify FDA in writing (see table 1 for Contact Person).

TABLE 1—ADVISORY COMMITTEE CONTACTS

Contact person	Committee/panel
Janie Kim, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6129, Silver Spring, MD 20993–0002, Phone: 301–796–9016, Email: *Janie.Kim@fda.hhs.gov*.	Cellular, Tissue and Gene Therapies.
Philip Bautista, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2410, Silver Spring, MD 20993–0002, Phone: 301–796–9006, Email: *Philip.Bautista@fda.hhs.gov*.	Drug Safety and Risk Management Advisory Committee.
Natasha Facey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1552, Silver Spring, MD 20993–0002, Phone: 301–796–5290, Email: *Natasha.Facey@fda.hhs.gov*.	Immunology Devices Panel.