FOR FURTHER INFORMATION CONTACT: Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6340, Silver Spring, MD 20993–0002, 301–796–1042; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009.'' This draft guidance provides answers to common questions from sponsors interested in developing proposed biosimilar products, BLA holders, and other interested parties regarding FDA's interpretation of the BPCI Act.

The BPCI Act, enacted as part of the Patient Protection and Affordable Care Act (Pub. L. 111–148) on March 23, 2010, created an abbreviated licensure pathway under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) for biological products demonstrated to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product. This draft guidance describes FDA's current interpretation of certain statutory requirements added by the BPCI Act and includes questions and answers (Q&As) in the following categories:

- Biosimilarity or Interchangeability
- Provisions Related to Requirement to Submit a BLA for a ''Biological Product''
- Exclusivity

The Q&A format is intended to promote transparency and facilitate development programs for proposed biosimilar products by addressing questions that may arise in the early stages of development. In addition, these Q&As respond to questions the Agency has received from prospective BLA and new drug application (NDA) applicants regarding the appropriate statutory authority under which certain products will be regulated.

FDA intends to update this guidance to include additional Q&As as appropriate and intends to post information by Q&A number on FDA's Web site regarding the publication date of draft guidance Q&As for comment, the comment period, and the publication date of final guidance Q&As.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. The Paperwork Reduction Act

This draft guidance describes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (the PRA) (44 U.S.C. 3501–3520). In particular, the draft guidance refers to information collections related to the submission of a 351(k) application. In accordance with the PRA, FDA is soliciting public comment, in a separate document published elsewhere in this issue of the **Federal Register** (see ''Agency Information Collection Activities; Proposed Collection; Comment Request; General Licensing Provisions; Section 351(k) Biosimilar Applications'') on the information collection associated with the submission of a 351(k) application. FDA will also seek OMB approval for this information collection.

In addition, this draft guidance references other information collections that are already approved by OMB and are not expected to change as a result of the draft guidance. This includes information collections related to the submission of (1) an investigational NDA, which is covered under 21 CFR part 312 and approved under OMB control number 0910–0014; (2) an NDA, which is covered under 21 CFR 314.50 and approved under OMB control number 0910–0001; (3) a biologics license application, which is covered under 21 CFR part 601 and approved under OMB control number 0910–0338; and (4) labeling, which is covered under 21 CFR 201.57 and approved under OMB control number 0910–0572.

The draft guidance also discusses the retention of reserve samples of the biological products used in comparative clinical pharmacokinetic and/or pharmacodynamic studies intended to support a proposed 351(k) application. Such reserve samples are samples of products or other physical objects exempt under 5 CFR 1320.3(h)(2), and thus not considered ''information'' as that term is defined under the PRA.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm*, *http://www.fda.gov/BiologicsBloodVaccines/GuidanceCompliance RegulatoryInformation/default.htm*, or *http://www.regulations.gov*.

Dated: *February 9, 2012.*

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–3549 Filed 2–14–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Detroit District Office, in co-sponsorship 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 (IRB). 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, IRB, and research sponsors.

Date and Time: The public workshop will be held on May 9 and 10, 2012, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Marriott Ann Arbor Ypsilanti at Eagle Crest, 1275 S. Huron St., Ypsilanti, MI 48197, 800–606–7044.

Contact: Society of Clinical Research Associates (SoCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914, 1–800–762–7292 or 215–822–8644, FAX: 215–822–8633, email: *SoCRAmail@aol.com,* Web site: *http://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**.); or Nancy Bellamy, Food and Drug Administration, Detroit District Office, 300 River Pl., Suite 5900, Detroit, MI 48207, 313–393–8143, Fax: 313–393–8139, email: *nancy.bellamy@fda.hhs.gov.*

Accommodations: Attendees are responsible for their own accommodations. Please mention SoCRA to receive the hotel room rate of $119 plus applicable taxes (available until April 17, 2012 or until the SoCRA room block is filled).

COST OF REGISTRATION

SoCRA member	$575
SoCRA nonmember (includes membership)	650
Federal Government member	450
Federal Government non-member	525
FDA Employee	*

* (Free) Fee Waived.

If you need special accommodations due to a disability, please contact SoCRA (see *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 educational activity for a maximum of 13.3 Continuing Education 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: 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, telephone, 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.* 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 *Contact*).

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, 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; (13) Ethical Issues in Subject Enrollment; (14) Medical Device Aspects of Clinical Research; (15) Are We There Yet? An Overview of the FDA GCP Program.

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 (Pub. L. 104–121) as outreach activities by Government Agencies to small businesses.

Dated: February 9, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–3553 Filed 2–14–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director Notice of Establishment

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. App), the Director, National Institutes of Health (NIH), announces the establishment of the National Center for Advancing Translational Sciences Advisory Council (Council) and the Cures Acceleration Network Review Board (Board), in the National Center for Advancing Translation Sciences (NCATS).

The Council will advise, assist, consult with, and make recommendations to the Secretary of Health and Human Services (Secretary), the Director, National Institutes of Health (NIH) and the Director, National Center for Advancing Translational Sciences (NCATS, also referred to as Center) on matters related to the activities carried out by and through the Center and the policies respecting these activities.

The Board will advise, and provide recommendation to, the Director, NCATS, with respect to (1) policies, programs, and procedures for carrying out the duties of the Director, NCATS, under section 480 of the PHS Act; and (2) significant barriers to successful translation of basic science into clinical application (including issues under the purview of other agencies and departments).

Duration of each committee is two years from the date the Charter is filed.

Dated: February 7, 2012.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2012–3572 Filed 2–14–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as