fluorescent or chromogenic enzyme-substrate detection methods (e.g., immunohistochemical stains) nor does it cover the use of flow cytometry for cell enrichment and cell sorting/purification when used in cell therapy product manufacturing.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on flow cytometric devices. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov* or from CBER at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* Persons unable to download an electronic copy of ''Flow Cytometric Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1787 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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, and will be posted to the docket at *http://www.regulations.gov.*

Dated: October 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–24308 Filed 10–10–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Society of Clinical Research Associates—Food and Drug Administration: Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing an educational conference co-sponsored with the Society of Clinical Research Associates (SoCRA). The public workshop regarding 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 November 5 and 6, 2014, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Wyndham Lake Buena Vista Hotel, 1850 Hotel Plaza Blvd., Lake Buena Vista, FL 32830, 407–828–4444.

Attendees are responsible for their own accommodations. Please mention SoCRA to receive the hotel room rate of $95.00 plus applicable taxes (available until October 6, 2014, or until the SoCRA room block is filled).

Contact: C. Stewart Watson, Food and Drug Administration, 555 Winderley Pl., Suite 200, Maitland, FL 32751, 407–475–4756, FAX: 407–475–4768, or Society of Clinical Research Associates (SoCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914, 800–762–7292 or 215–822–8644, FAX: 215–822–8633, email *SoCRAmail@aol.com,* Web site: *www.socra.org.*

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—$450.00; Federal Government SoCRA nonmember—$525.00; FDA Employee—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 education activity for a maximum of 13.3 continuing education (CE) credits for SoCRA CE and continuing nursing education (CNE). SoCRA designates this live activity for a maximum of 13.3 American Medical Association Physicians Recognition Award Category 1 Credit(s).™ Physicians should claim only the credit commensurate with the extent of their participation. *Continuing Medical Education 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.* (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 is published in the **Federal Register**.) 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 public workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements related informed consent, clinical investigation requirements, institutional review board inspections, electronic record requirements, and investigator initiated research 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 Programs; (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; (16) Question and Answer Session/Panel Discussion.

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

Dated: October 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–24307 Filed 10–10–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Evaluation of National Institutes of Health International Bilateral Programs (FIC, NCI, NIAAA, NIAID, NICHD, NIDA, NINDS, NIMH, OAR)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 13, 2014 (Vol. 79, P. 14256) and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

DATES: *Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Margaret Mary Bertram, Center for Global Health, National Cancer Institute, 9609 Medical Center Dr., Rm 3W264, Rockville MD, 20850 or call non-toll-free number 240–276–5656 or Email your request, including your address to: *margaret.bertram@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Evaluation of National Institutes of Health International Bilateral Programs (FIC, NCI, NIAAA, NIAID, NICHD, NIDA, NINDS, NIMH, OAR), 0925–NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This submission is a request for OMB to approve the Evaluation of National Institutes of Health (NIH) International Bilateral Programs for three years. The bilateral awards are made through the Funding Opportunity Announcement mechanism and administrative supplements, meaning they are funded by set-aside funds that are separate from the general pool of research program grant funds used to support investigator initiated research at NIH. The bilateral programs to be evaluated are the U.S.-China Program for Biomedical Research Cooperation, U.S.-India Bilateral Collaborative Research Partnerships on the Prevention of HIV/AIDS and Co-morbidities, U.S.-Russia Bilateral Collaborative Research Partnerships on the Prevention and Treatment of HIV/AIDS and Co-morbidities, and U.S.-South Africa Program for Collaborative Biomedical Research. These programs are funded and administered by various combinations of the following institutes: Fogarty International Center (FIC), the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Cancer Institute (NCI), National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institute for Allergy and Infectious Diseases (NIAID), National Institute on Drug Abuse (NIDA), National Institute of Mental Health (NIMH), National Institute of Neurological Disorders and Stroke (NINDS), and the Office of AIDS Research (OAR). While these programs differ, their underlying concept is the same; they require U.S. scientists to collaborate with scientists from other countries in order to conduct scientifically meritorious investigations of mutual interest to both countries. The proposed evaluation requests information about (1) accomplishments of the awards, (2) unique findings or opportunities due to the international collaborations, and (3) successes and challenges of these collaborations. The information will be collected one year into the award and at the end of the award, when possible. This information is needed to evaluate the effectiveness of these programs across NIH.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 129.