672, Bethesda, MD 20892, 301–594–4859, *makridessc@mail.nih.gov.*

Name of Committee: National Institute of Dental and Craniofacial Research; Special Emphasis Panel, Oral Health Disparities in Children: Data Coordinating Center (U01).

Date: May 6, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Crowne Plaza Washington National Airport, 1489 Crystal Drive, Arlington, VA 20220.

Contact Person: Jayalakshmi Raman, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Dental and Craniofacial Research, One Democracy Plaza, Room 670, Bethesda, MD 20892–4878, 301–594–2904, *ramanj@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: March 31, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–07739 Filed 4–3–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 13, 2015, from 8 a.m. to 5:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm.1503), Silver Spring, MD 20993–0002. For those unable to attend in person, the meeting will also be available via Web cast. The Web cast will be available at the following link: *https://collaboration.fda.gov/bpac2015/.* When accessing the Web cast please enter as a guest. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

Contact Person: Bryan Emery or Joanne Lipkind, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6132, Silver Spring, MD 20993–0002, 240–402–8054 or 240–402–8129, or FDA Advisory Committee Information Line, (1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On May 13, 2015, the Blood Products Advisory Committee will meet in open session to discuss strategies for implementation of serological and nucleic acid testing for *Babesia microti* in blood donors. In the afternoon, the committee will hear update presentations on the following topics: (1) FDA considerations for Hemoglobin S Testing in blood donors; and (2) FDA considerations for a revised blood donor deferral policy for men who have sex with men. Following the update presentations, the committee will hear presentations on the research programs of the Laboratory of Cellular Hematology, Division of Hematology Research and Review, Office of Blood Research and Review, Center for Biologics Evaluation and Research, FDA.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: On May 13, 2015, from 8:30 a.m. to approximately 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 6, 2015. Oral presentations from the public on May 13, 2015, will be scheduled between approximately 11:15 a.m. and 12:15 p.m. and 4:30 p.m. until 5 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 28, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 29, 2015.

Closed Committee Deliberations: On May 13, 2015, from approximately 5 p.m. to 5:30 p.m., the meeting will be closed to the public to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c) (6)). The committee will discuss the site visit report of the intramural research programs of the Laboratory of Cellular Hematology and make recommendations regarding personnel staffing decisions.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets. Seating for this meeting may be limited, so the public is encouraged to watch the free Web cast if you are unable to attend. The Web cast will be available at 8:30 a.m. on May 13, 2015, at the link provided.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Bryan Emery at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 31, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–07816 Filed 4–3–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) is announcing an educational conference cosponsored with the Society of Clinical Research Associates (SOCRA). The public conference 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 (IRBs). Individual FDA representatives will discuss the informed consent process including informed consent documents, regulations relating to drugs, devices, and biologics, as well as inspections of clinical investigators, IRBs, and research sponsors.

Date and Time: The public conference will be held on May 13 and 14, 2015, from 8 a.m. to 5 p.m.

Location: The conference will be held at The Westin Cincinnati, 21 East Fifth Street, Cincinnati, OH 45202; 513–621–7700. Attendees are responsible for their own accommodations. Please mention SOCRA to receive the hotel room rate of $169 plus applicable taxes (available until April 15, 2015, or until the SOCRA room block is filled).

Contact: John Fraser, Cincinnati District Office, Food and Drug Administration, 6751 Steger Dr., Cincinnati OH 45237, 513–679–2700, FAX: 513–679–2771 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: *Office@socra.org*, 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**.)

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; 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 education activity for a maximum of 13.3 Continuing Education (CE) Credits for SOCRA CE and Continuing Nurse 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*. 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, 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; (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 the 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 workshop helps to achieve objectives set forth in section 406 of the Food and Drug Administration 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: April 1, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–07810 Filed 4–3–15; 8:45 am]

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