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

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

Dated: July 12, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–18063 Filed 7–18–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Arthritis 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). The meeting will be open to the public.

Name of Committee: Arthritis 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 September 13, 2011, from 8 a.m. to 5:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Philip A. Bautista, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, e-mail: *AAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On September 13, 2011, the committee will discuss the anti-nerve growth factor (Anti-NGF) drug class that is currently under development and the safety issues possibly related to these drugs. These drugs are being developed for the treatment of a variety of chronic painful conditions including osteoarthritis, chronic lower back pain, diabetic peripheral neuropathy, post-herpetic neuralgia, chronic pancreatitis, endometriosis, interstitial cystitis, vertebral fracture, thermal injury, and cancer pain. The committee will be asked to determine whether reports of joint destruction represent a safety signal related to the Anti-NGF class of drugs, and whether the risk benefit balance for these drugs favors continued development of the drugs as analgesics.

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 link.

Procedure: 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 August 29, 2011. Oral presentations from the public will be scheduled between approximately 1:30 and 2:30 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 August 19, 2011. 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 August 22, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

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 Philip A. Bautista 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 meetings.

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

Dated: July 13, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–18062 Filed 7–18–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Quarantine Release Errors in Blood Establishments; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: ''Quarantine Release Errors in Blood Establishments.'' The purpose of this public workshop is to provide a forum for discussion of quarantine release errors (QREs) and provide FDA and industry with information necessary to reduce the rates of QREs. The workshop will focus on the extent and characteristics of QREs in blood establishments and the specifications of blood establishment computer software

(BECS) as they relate to inventory control. The public workshop has been planned in partnership with the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Health, America's Blood Centers, and AABB. This public workshop will include presentations and panel discussions by experts knowledgeable in this field from government Agencies and industry.

Date and Time: The public workshop will be held on September 13, 2011, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at the Universities at Shady Grove Conference Center, 9630 Gudelsky Dr., Rockville, MD 20850–5820, 301–738–6000.

Contact Person: Rhonda Dawson, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6129, FAX: 301–827–2843, e-mail: *rhonda.dawson@fda.hhs.gov.*

Registration: Mail, fax, or e-mail your registration information (including name, title, firm name, address, telephone, and fax numbers) to Rhonda Dawson (see *Contact Person*) by September 1, 2011. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Rhonda Dawson (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: QREs refer to the inadvertent release of blood or blood components either before completion of testing and determination that all other criteria affecting the safety, purity, or potency of the product have been met, or despite findings that would render the blood or blood components unsuitable for release. Although QREs that result in the distribution of blood or blood components are required to be reported to FDA as biologic product deviation reports (BPDRs), the amount of information provided in BPDRs varies and often represents a summary of information rather than a detailed description and analysis of the problem. Thus, the root causes of QREs are not known with certainty. Further, the rates of QREs are also not known with certainty, and actions necessary to correct and prevent them are unclear.

There has been a recent focus on QREs related to the release of units with incomplete or absent testing for transfusion-transmitted infectious diseases. On June 10 and 11, 2010, the HHS Advisory Committee on Blood Safety and Availability (the Committee) met to discuss the current FDA blood donor deferral policy on men who have sex with other men. While the Committee recommended that the current deferral policy not be changed at the present time, it found the current policy to be suboptimal in permitting some potentially high risk donations while preventing some low risk donations. The Committee made a number of recommendations and indicated that HHS should take action to investigate and reduce the risk of QREs in blood collection establishments.

This public workshop will serve as a forum for discussion of QREs and provide FDA and industry with information necessary to reduce the rates of QREs. The public workshop presentations and panel discussions will: (1) Review recent BPDR data to better determine the root causes for QREs and identify activities that could address those causes; (2) evaluate the use of 510(k) cleared BECS or implementation of BECS performance standards in reducing the rate of QREs; and (3) explore other potential strategies to address QREs. The public workshop will conclude with a summary of the issues discussed.

Transcripts: Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible on the Internet at: *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm.* Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857.

Dated: July 13, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–18093 Filed 7–18–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Effects of Ischemia Reperfusion Injury on Outcomes in Kidney Transplantation; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop to discuss the effects of ischemia/reperfusion injury (IRI) on outcomes in kidney transplantation. This public workshop is intended to obtain information from health care providers, academia, and industry on various aspects of the pathophysiology, clinical management, and outcomes following IRI. The meeting will include a discussion of animal models, devices, and clinical trial design. The input from this public workshop will help in developing topics for further discussion and may serve to inform recommendations on clinical trial design for products for the mitigation of IRI and/or for the prophylaxis and/or treatment of delayed graft function (DGF) and related conditions in kidney transplant recipients.

Date and Time: The public workshop will be held on September 8, 2011, from 9 a.m. to 6 p.m. and on September 9, 2011, from 8 a.m. to 3 p.m.

Location: The public workshop will be held at the Crowne Plaza, 8777 Georgia Ave., Silver Spring, MD 20910, 301–589–0800. Seating is available only on a first-come-first-served basis.

Contact Persons: Christine Moser or Ramou Mauer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6209, Silver Spring, MD 20993–0002, 301–796–1300 or 301–796–1600.

Registration: Registration is free for the public workshop. Interested parties are encouraged to register early because space is limited. Seating will be available on a first-come-first-served basis. To register electronically, e-mail registration information (including name, title, firm name, address, telephone, and fax number) to *IRIworkshop@fda.hhs.gov.* Persons without access to the Internet can call Christine Moser, 301–796–1300, or Ramou Mauer, 301–796–1600, to register.

Persons needing a sign language interpreter or other special accommodations should notify Christine Moser or Ramou Mauer (see *Contact Persons*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop regarding effects of IRI on outcome in kidney transplantation and medical product development for the prevention and/or treatment of DGF in kidney transplant recipients. This public workshop will include scientific discussion on the following topics: