

which may lead to various modes of toxicities. Furthermore, both nickel ion release and corrosion characteristics are dependent on surface finishing for nitinol as well as for some other nickel-containing alloys. Through the collection of information from a pre-workshop work assignment and discussions with workshop participants, FDA will be able to better determine what assessments may be considered for cardiovascular implants made of commonly used metallic alloys, and this information is expected to serve as the foundation for a future guidance document.

II. Topics for Discussion at the Public Workshop

The objective of this workshop is to provide a forum for discussion of the following topics:

- The various methods that are used for corrosion assessments, surface characterization techniques, and nickel leach testing used to evaluate the suitability of metallic cardiovascular implant devices;
- The limitations of each of these tests to predict actual in vivo performance;
- The need and utility for each test; and
- The potential testing paradigms, including when certain tests should be considered, and how to establish acceptance criteria for each test.

III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm> (select this public workshop from the posted events list), approximately 45 days after the public workshop.

Dated: February 1, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-2583 Filed 2-3-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Organ Transplantation; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: Advisory Committee on Organ Transplantation (ACOT).

Date And Time: February 28, 2012, 10 am to 4 p.m. Eastern Standard Time (EST).

Place: The meeting will be via audio conference call and Adobe Connect Pro.

Status: The meeting will be open to the public.

Purpose: Under the authority of 42 U.S.C. Section 217a, Section 222 of the Public Health Service Act, as amended, and 42 CFR 121.12 (2000), ACOT was established to assist the Secretary in enhancing organ donation, ensuring that the system of organ transplantation is grounded in the best available medical science, and assuring the public that the system is as effective and equitable as possible, thereby, increasing public confidence in the integrity and effectiveness of the transplantation system. ACOT is composed of up to 25 members, including the Chair. Members are serving as Special Government Employees and have diverse backgrounds in fields such as organ donation, health care public policy, transplantation medicine and surgery, critical care medicine and other medical specialties involved in the identification and referral of donors, non-physician transplant professions, nursing, epidemiology, immunology, law and bioethics, behavioral sciences, economics and statistics, as well as representatives of transplant candidates, transplant recipients, organ donors, and family members.

Agenda: The Committee will hear reports from the three ACOT Work Groups: Declining Rates of Donation/Geographical and Other Variations in Organ Distribution, Alignment of CMS Regulatory Requirements with OPTN and HRSA, and Brain Death Determination. ACOT presentations will include transplant tourism, and a report of the Technical Expert Panel on death determination in Uncontrolled Donation after Circulatory Determination of Death (UDCDD). Agenda items are subject to change as priorities indicate.

After presentations and Committee discussions, members of the public will have an opportunity to provide comments. Because of the Committee's full agenda and timeframe in which to cover the agenda topics, public comment will be limited. All public comments will be included in the record of the ACOT meeting. Meeting Summary notes will be posted on the Department's donation Web site at <http://www.organdonor.gov/legislation/advisory.html#meetings>. The draft meeting agenda will be posted on <http://www.team-psa.com/ACOT/February2012>.

The public can join the meeting by:

1. [Audio Portion] Calling the Conference Phone Number (888-790-3384) and providing the Participant Code (6216514), AND

2. [Visual Portion] Connecting to the ACOT Adobe Connect Pro Meeting using the following URL: <https://hrsa.connectsolutions.com/acot-22812/> (copy and paste the link into your browser if it does not work directly, and enter as a guest). The conference call leader is Patricia A. Stroup.

Call (301) 443-0437 or send an email to ptongele@hrsa.com if you are having trouble connecting to the meeting site. Participants should call and connect to the meeting no later than 9:45 a.m. EST in order for logistics to be set up. If you have never attended an Adobe Pro Connect Meeting, please test your connection using the following URL: https://hrsa.connectsolutions.com/common/help/en/support/meeting_test.htm. For a quick overview, please access: http://www.adobe.com/go/connectpro_overview.

Those planning on attending this conference call should register by contacting Brittany Carey, the Logistical Coordinator, at bcarey@explorepesa.com (or by telephone at (703) 889-9033) before the registration deadline of February 24, 2012.

Public Comment: It is preferred that persons interested in providing an oral presentation submit a written request, along with a copy of their presentation to: Passy Tongele, Division of Transplantation, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 12C-06, 5600 Fishers Lane, Rockville, Maryland 20857. Requests and presentations also may be emailed to ptongele@hrsa.gov. Requests should contain the name, address, telephone number, email address, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative.

Persons may also request to speak at the time of the public comment period. Public participation and ability to comment may be limited as time permits.

FOR FURTHER INFORMATION CONTACT:

Patricia Stroup, Executive Secretary, ACOT, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 12C-06, Rockville, Maryland 20857; telephone (301) 443-1127.

Dated: January 31, 2012.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2012-2646 Filed 2-3-12; 8:45 am]

BILLING CODE 4165-15-P