TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| FD&C Act section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| 502(u) | 10 | 100 | 1,000 | .1 | 100 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: February 1, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2012–2555 Filed 2–3–12; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–N–0001]**

### Oncologic Drugs 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:* Oncologic Drugs 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 March 21, 2012, from 8 a.m. to 12:45 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. 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:* Caleb Briggs, 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, email: *ODAC@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:* The committee will discuss new drug application (NDA) 202497, MARQIBO (vincristine sulfate liposomes injection), application submitted by Talon Therapeutics, Inc. The proposed indication (use) for this product is for the treatment of adult patients with Philadelphia chromosome-negative acute lymphoblastic leukemia in second or greater relapse or whose disease has progressed following two or more treatment lines of anti-leukemia therapy.

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 March 6, 2012. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:45 a.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 February 27, 2012. 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 February 28, 2012.

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 Caleb Briggs 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: January 31, 2012.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2012–2460 Filed 2–3–12; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–N–0057]**

### Cardiovascular Metallic Implants: Corrosion, Surface Characterization, and Nickel Leaching; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Cardiovascular Metallic Implants: Corrosion, Surface Characterization, and Nickel Leaching.'' The purpose of this public workshop is to provide a forum for FDA, cardiovascular device manufacturers, test houses, and academia to discuss corrosion, surface characterization, and nickel leach testing, as well as to collect comments and input regarding when these assessments should be considered.

*Dates and Time:* The public workshop will be held on March 8 and 9, 2012, from 9 a.m. to 5:30 p.m. EST.

*Location:* The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503 (the Great Room), Silver Spring, MD 20993. For parking and security information, please visit the following Web site: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.* The public workshop will also be available to be viewed online via webcast.

*Contact Persons:*

Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, (301) 796–6353, FAX: (301) 796–9959, email: *erica.takai@fda.hhs.gov;* or

Nicole Ibrahim, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, (301) 796–5171, email: *nicole.ibrahim@fda.hhs.gov.*

*Registration:* To register for the public workshop, please visit the following Web site: *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (or go to *http://www.fda.gov* and select the FDA Medical Devices News & Events—Workshops & Conferences calendar and select this public workshop from the posted events list). Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. For those without Internet access, please call the *Contact Person* to register. Registration is mandatory as space is limited and onsite registration will not be available. FDA may limit the number of participants from each organization. There is no registration fee for the public workshop. Registration requests should be received by 5 p.m. E.S.T. on February 21, 2012.

If you need special accommodations due to a disability, please contact Susan Monahan, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4321, Silver Spring, MD 20993, (301) 796–5661 or email: *susan.monahan@fda.hhs.gov* at least 7 days in advance of the workshop.

*Streaming Webcast of the Public Workshop:* This workshop will also be webcast. Persons interested in viewing the webcast must register online by 5 p.m. E.S.T. on February 21, 2012. Early registration is recommended because webcast connections are limited. Organizations are requested to register all participants, but view using one connection per location. Webcast participants will be sent technical system requirements after registration, and will be sent connection access information in a final confirmation email by 5 p.m. E.S.T. on March 2, 2012. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**).

*Workshop Participation:* Participation in the workshop will consist of both lead participants and audience members. Lead participants will include representatives from various organizations involved in or who perform corrosion testing, surface characterization, and/or nickel leach testing and toxicological assessments of nickel, such as industry, the medical community, and test houses, and will be driving the discussions. Lead participants are expected to complete a work assignment in advance of the workshop in order to optimize the time spent during the workshop. FDA will compile the work assignment responses prior to the workshop so that any information provided from the responding organization is de-identified.

If you wish to participate as a lead participant, you must indicate this at the time of registration. There will be a tentative limit of one lead participant per organization for industry and two for test houses for each session, with a total workshop participation limit of two industry participants and three for test houses, due to space limitations. Audience members may be able to participate in discussions, if time permits.

*Additional Information:* Background information on the public workshop, registration information, agenda, information about lodging, food services, and other relevant information will be posted, as it becomes available, on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (or go to *http://www.fda.gov* and select the FDA Medical Devices News & Events—Workshops and Conferences calendar and select this public workshop from the posted events list).

*Comments:* FDA is holding this public workshop to obtain information on a number of questions regarding corrosion, surface characterization, and nickel leaching. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting written or electronic comments on all aspects of the workshop topics. The deadline for submitting comments related to this public workshop is April 6, 2012.

Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments. Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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. In addition, when responding to specific topics as outlined in section II of this document, please identify the topic you are addressing. 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.*

**SUPPLEMENTARY INFORMATION:**

## I. Background and Objectives

While the majority of cardiovascular implants are made of metals and may be susceptible to corrosion, it is unclear whether the current corrosion testing paradigm is predictive of in vivo corrosion outcomes, or if there may be more suitable assessments to predict corrosion failure. In addition, there has been an increase in the use of nitinol, a nickel-titanium alloy, in cardiovascular implants due to its superelastic properties, which are ideal for transcatheter-delivered therapies. Corrosion of implant devices made of nitinol and other nickel-containing metal alloys (*e.g.* stainless steel, MP35N) results in the release of nickel ions,

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@explorepsa.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**