

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 June 13, 2012, the committee will discuss, make recommendations and vote on information related to the premarket approval application for the Edwards SAPIEN Transcatheter Heart Valve sponsored by Edwards Lifesciences. The Edwards SAPIEN Transcatheter Heart Valve is indicated for use in patients with symptomatic severe aortic stenosis who have high operative risk.

The Edwards SAPIEN Transcatheter Heart Valve, model 9000TFX, sizes 23mm and 26mm and accessories implant system consists of the following:

- A heterologous (bovine) pericardium leaflet valve sutured within a stainless steel mesh frame, with a polyester skirt. It is offered in two sizes, a 23 mm and a 26 mm.
- The RetroFlex 3 Delivery System is used to advance the bioprosthesis through the RetroFlex sheath over a guidewire and to track the bioprosthesis over the aortic arch and for crossing and positioning in the native valve. The delivery system also comes with a sheath, introducer, loader, dilator, balloon (used to pre-dilate the native annulus) and a crimper.

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:** 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 June 5, 2012. On June 13, 2012, oral presentations from the public will be scheduled between approximately 1 p.m. and 2 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 May 29, 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 June 1, 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 James Clark, Conference Management Staff, at [James.Clark@fda.hhs.gov](mailto:James.Clark@fda.hhs.gov) or 301-796-5293 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: April 19, 2012.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2012-10156 Filed 4-26-12; 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 June 20, 2012, from 8 a.m. to 5 p.m.

**Location:** FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center, (Rm. 1503), 10903 New Hampshire Avenue, 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, Pharm.D., Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., WO31-2417, Silver Spring,

MD 20993-0002, (301) 796-9001, Fax: (301) 847-8533, email: [ODAC@fda.hhs.gov](mailto:ODAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. 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 advisory committee information line or visit our Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> to learn about possible modifications before coming to the meeting.

**Agenda:** On June 20, 2012, during the morning session, the committee will discuss new drug application (NDA) 203213, with the established name semuloparin sodium injection, application submitted by sanofi-aventis U.S. LLC. The proposed indication (use) for this product is for the prophylaxis of venous thromboembolism (VTE) in patients receiving chemotherapy for locally advanced or metastatic pancreatic or lung cancer or for locally advanced or metastatic solid tumors with a VTE risk score  $\geq 3$ .

During the afternoon session, the committee will discuss NDA 202714, with the proposed trade name Kyprolis (carfilzomib) for injection, application submitted by Onyx Pharmaceuticals, Inc. The proposed indication (use) for this product is for the treatment of patients with relapsed and refractory (recurring and/or not responsive to other treatments) multiple myeloma who have received at least 2 prior lines of therapy that included a proteasome inhibitor and an immunomodulatory agent.

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 June 6, 2012. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m., and 3:30 p.m. to 4 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 May 29, 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 May 30, 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: April 19, 2012.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2012-10154 Filed 4-26-12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Complementary and Alternative Medicine; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council for Complementary and Alternative Medicine.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which

would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Advisory Council for Complementary and Alternative Medicine.

*Date:* June 1, 2012.

*Closed:* 8:30 a.m. to 10 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

*Open:* 10:15 a.m. to 4 p.m.

*Agenda:* A report from the Institute Director and other staff.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

*Contact Person:* Martin H. Goldrosen, Ph.D., Director, Division of Extramural Activities, National Center for Complementary and Alternative Medicine, NIH, 6707 Democracy Blvd., Ste. 401, Bethesda, MD 20892-5475, (301) 594-2014, [goldrosen@mail.nih.gov](mailto:goldrosen@mail.nih.gov).

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: [nccam.nih.gov/about/naccam/](http://nccam.nih.gov/about/naccam/), where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: April 20, 2012.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2012-10130 Filed 4-26-12; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2012-0013]

### Agency Information Collection Activities: Submission for Review; Information Collection Extension Request for the DHS S&T First Responders Community of Practice Program

**AGENCY:** Science and Technology Directorate, DHS.

**ACTION:** 60-day Notice and request for comment.

**SUMMARY:** The Department of Homeland Security (DHS) invites the general public to comment on the data collection form for the DHS Science & Technology (S&T) First Responders Community of Practice (FRCoP): User Registration Page (DHS Form 10059 (9/09)). The FRCoP web based tool collects profile information from first responders and select authorized non-first responder users to facilitate networking and formation of online communities. All users are required to authenticate prior to entering the site. In addition, the tool provides members the capability to create wikis, discussion threads, blogs, documents, etc., allowing them to enter and upload content in accordance with the site's Rules of Behavior. Members are able to participate in threaded discussions and comment on other member's content. The DHS S&T FRCoP Program is responsible for providing a collaborative environment for the first responder community to share information, best practices, and lessons learned. Section 313 of the Homeland Security Act of 2002 (Pub. L. 107-296) established this requirement. This notice and request for comments is required by the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chapter 35). This notice and request for comments is required by the Paperwork Reduction Act of 1995 (Pub. Law 104-13, 44 U.S.C. chapter 35).

**DATES:** Comments are encouraged and will be accepted until June 26, 2012.

**ADDRESSES:** Interested persons are invited to submit comments, identified by docket number DHS-2012-0013, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Please follow the instructions for submitting comments.

- *Email:* [Kathy.Higgins@hq.dhs.gov](mailto:Kathy.Higgins@hq.dhs.gov). Please include docket number DHS-2012-0013 in the subject line of the message.

- *Fax:* (202) 254-6171. (Not a toll-free number).

- *Mail:* Science and Technology Directorate, Attn: Chief Information