

*Total Annual Hours:* 365,136. (For policy questions regarding this collection contact William Lehrman at 410-786-1037. For all other issues call 410-786-1326.)

## 2. Type of Information Collection

*Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Site Investigation for Durable Medical Equipment (DME) Suppliers; *Use:* CMS is mandated to identify and implement measures to prevent fraud and abuse in the Medicare program. To meet this challenge, CMS has moved forward to improve the quality of the process for enrolling suppliers into the Medicare program by establishing a uniform application for enumerating suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Implementation of enhanced procedures for verifying the enrollment information has also improved the enrollment process. As part of this process, verification of compliance with supplier standards is necessary. The site investigation form has been used in the past to aid the Medicare contractor (the National Supplier Clearinghouse and/or its subcontractors) in verifying compliance with the required supplier standards found in 42 CFR 424.57(c). The primary function of the site investigation form is to provide a standardized, uniform tool to gather information from a DMEPOS supplier that tells us whether it meets certain qualifications to be a DMEPOS supplier (as found in 42 CFR 424.57(c)) and where it practices or renders its services.

This site investigation form collects the same information as its predecessor, with the exception of one new yes/no question under the "Records and Telephone" section (question 11(a)) used to verify if the DMEPOS supplier maintains physician ordering/referring records for the supplies and/or services it renders to Medicare beneficiaries (if applicable). This information is required by section 1833(g) of the Social Security Act (the Act) which states that all physicians and non-physician practitioners that meet the definitions at section 1861(r) and 1842(b)(18)(C) of the Act, be uniquely identified for all claims for services that are ordered or referred. Other information collected on this site investigation remains unchanged, but has been reformatted for greater functionality. *Form Number:* CMS-R-263 (OCN: 0938-0749); *Frequency:* Once; *Affected Public:* Private Sector—Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 30,000; *Total Annual Responses:* 30,000; *Total Annual Hours:*

15,000. (For policy questions regarding this collection contact Kimberly McPhillips at 410-786-5374. For all other issues call 410-786-1326.)

## 3. Type of Information Collection

*Request:* Revision of a currently approved collection;

*Title of Information Collection:* Medicare Registration Application; *Use:* The CMS 855O allows a physician to receive a Medicare identification number (without being approved for billing privileges) for the sole purpose of ordering and referring Medicare beneficiaries to Medicare approved providers and suppliers. This new Medicare registration application form allows physicians who do not provide services to Medicare beneficiaries to be given a Medicare identification number without having to supply all the data required for the submission of Medicare claims. It also allows the Medicare program to identify ordering and referring physicians without having to validate the amount of data necessary to determine claims payment eligibility (such as banking information), while continuing to identify the physician's credentials as valid for ordering and referring purposes. Since the physicians and non-physician practitioners submitting this application are not enrolling in Medicare to submit claims but are only registering with Medicare as eligible to order and refer, CMS believes changing the title from Medicare Enrollment Application to Medicare Registration Application better captures the actual purpose of this form.

Where appropriate, CMS has changed all references to enrollment or enrolling to registration and registering and Medicare billing number to National Provider Identifier. CMS also added a check box to allow physicians and non-physician practitioners to withdraw from the ordering and referring registry. A section to collect information on professional certifications was added for those practitioners who are not professionally licensed. Editorial and formatting corrections were made in response to prior comments received during the approval of the current version of this application. Other minor editorial and formatting corrections were made to better clarify the purpose of this application. *Form Number:* CMS-855(O) (OCN: 0938-1135); *Frequency:* Occasionally; *Affected Public:* Individuals; *Number of Respondents:* 48,500; *Total Annual Responses:* 48,500; *Total Annual Hours:* 24,125. (For policy questions regarding this collection contact Kimberly McPhillips at 410-786-5374. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on May 29, 2012.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-6974, Email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

Dated: April 24, 2012.

**Martique Jones,**

*Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.*

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0001]

### Circulatory System Devices Panel of the Medical Devices 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:* Circulatory System Devices Panel of the Medical Devices 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 13, 2012, from 8 a.m. to 6 p.m.

*Location:* Hilton Washington DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel telephone number is 301-977-8900.

*Contact Person:* Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 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 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.*

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**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